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Test Report

Report Number: SSMT-R-2020-00803-02

Sample Name: Disposable Medical Mask

Study Title: Skin Irritation Test

Standard: ISO 10993-10:2010

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

Zhejiang The Purples Protective Products Co.,Ltd.

1/F, North Zone, No.66, Qunying Road, Houzhai, Yiwu, Zhejiang Province

Contents

Explanation

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.
6. This experiment was carried out in the sub-site and the address is: No. 68, Yaoluo Road, Wujin District, Changzhou City.

Conclusion

The animal skin irritation test was conducted to assess the potential irritation of the test article.

Cut the sample into 2.5 cm×2.5 cm pieces and then applied them to the rabbit skin for 4 hours. Observation for erythema and edema were conducted at 1 h, 24 h, 48 h and 72 h after removal of the patches.

The skin reaction on test sites did not exceed that on the control sites. The primary irritation index for the test article was calculated to be 0.

The test result showed that the applied sample did not induce skin irritation in rabbit under the test condition.

Study verification and signature

The study was carried out in accordance with the standard operating procedure. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (ISO/IEC17025:2017, IDT) and RB/T214-2017.

Date Received	2020-04-13
Technical Initiation Date	2020-05-11
Technical Completion Date	2020-05-14
Final Report Completion Date	2020-05-21

Edited by Molly 2020.05.21
Date

Checked by Suri 2020.05.21
Date

Approved by Daisy 2020.05.22
Authorized signatory Date

Jiangsu Science Standard Medical Testing Co., Ltd.

1.0 Purpose

New Zealand rabbits were used to evaluate the potential of the sample for skin irritation under test conditions.

2.0 Reference

Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization(ISO 10993-10:2010)

Biological evaluation of medical devices-Part 12:Sample preparation and reference materials(ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

3.0 Test and control articles

3.1 Test article (The information about the test article was supplied by the sponsor wherever applicable.)

Test article name: Disposable Medical Mask

Sterilization state: Unsterilized

Model: TP-100

Size: 17.5cm*9.5cm

Lot/ Batch#: N/S

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

Solubility: N/S

Test Article Material: N/S

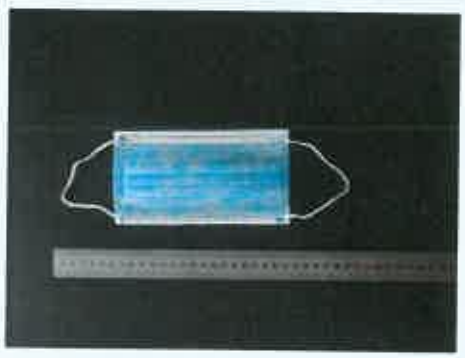
Packing Material: N/S

Storage Condition: Room Temperature

Manufacturer: Zhejiang The Purples Protective Products Co.,Ltd.

Manufacturer address: 1/F, North Zone, No.66, Qunying Road, Houzhai, Yiwu, Zhejiang Province

Sample photograph:



3.2 Control Article

Name: Medical gauze dressing

Manufacturer: Jiangxi David Medical Devices Co., Ltd.

Size: 5cm×7cm×8 layers

Lot/ Batch#: 20181102

Physical State: Solid

Color: White

Storage Condition: Room Temperature

4.0 Identification of test system

Species: New Zealand white rabbit

Number: 3

Sex: Female

Weight: Initial body weight not less than 2.0 kg

Health status: Healthy, young adult, nulliparous and not pregnant.

Housing: Animals were housed in groups in cages identified by a card indicating the lab number and test code.

Animal identification: Cage card

Quarantine: 5 days

5.0 Animal Care and Maintenance

Animal purchase: Provided by Tongxiang Yinhai Animal Husbandry Professional Cooperative <Permit Code: SCXK (ZHE) 2018-0002>

Bedding: NA

Feed: Rabbit Diet, Beijing Keao Xieli Feed Co., Ltd.

Water: Drinking water met the Standards for Drinking Water Quality (GB 5749-2006).

Cages: Stainless steel cage, Suzhou Fengqiao purification equipment Co., Ltd.

Environment: Temperature 16-26℃, Relative humidity 40%-70%.

Personnel: Associates involved were appropriately qualified and trained.

Selection: Only healthy were selected.

Veterinarian: Vet takes care of the whole course.

Ethics: Test methods of operation were reviewed and approved by the Commission on Science Standard animal ethics.

There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data.

6.0 Justification of the test system

6.1 The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. Positive control 15 % sodium dodecyl sulfate has been substantiated at SSMT with this method. Positive control test is conducted every six months. The last irritation index of polar test group was 5.5. The data was from the report SSMT-R-2018-00064-11 (Date: 2019-11-28); The last irritation index of non-polar test group was 5.7. The data was from the report SSMT-R-2018-00064-12 (Date: 2019-11-28).

6.2 The test article extract was directly applied to the rabbit skin, which is considered to be the best mean of

contact.

7.0 Equipment and Reagents

Electronic balance (SSMT-075)

8.0 Experiment design and dose

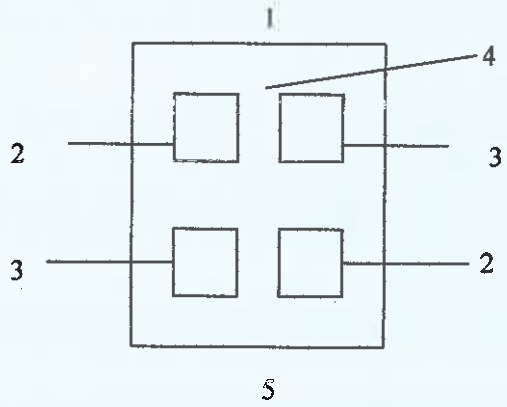
8.1 Sample preparation

The test sample and the control sample were cut randomly into 2.5 cm × 2.5 cm size and wetted with 0.9% sodium chloride injection.

8.2 Test method

Use the rabbits with healthy intact skin. Fur was generally clipped 16 h before testing on the backs of the rabbits, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10 × 15 cm).

Apply the sample and the negative control to the skin on each side as shown in Figure 1. And then wrap the application site with a bandage (semi-occlusive) for 4 h. At the end of the contact time, remove the dressings.



1- Cranial end, 2- Test site, 3- Control site, 4- Clipped dorsal region, 5- Caudal end

Figure1 Location of skin application sites

8.3 Observation of animal

Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 1 for each application site at each time interval. Record the appearance of each application site at 1 h,24 h, 48 h and 72 h following removal of the patches.

Table 1 Classification System for Skin Reaction

Reaction	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-defined by definite raising)	2
Moderate oedema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	**8**

NOTE: Other adverse changes at the skin sites were recorded and are reported.

8.4 Result calculation

Use only 24 h, 48 h and 72 h observations for calculation.

After the 72 h grading, all erythema grades plus oedema grades 24 h, 48 h and 72 h are totalled separately for each test sample and blank for each animal. The primary irritation score for an animal is calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).

To obtain the primary irritation index for the test sample add all the primary irritation scores of the individual animals and divide by the number of animals.

Calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.

9.0 Evaluation criteria

The primary irritation index is characterized by number (score) and description (response category) given in Table 2.

Table 2 Primary irritation index categories in a rabbit

Mean score	Response category
0-0.4	Negligible
0.5-1.9	Slight
2.0-4.9	Moderate
5-8	Severe

10.0 Results of the test

According to what observed, the response of skin on testing side did not exceed that on the control side. The primary irritation index for the test article was calculated to be 0. See Table 3.

Table 3 Dermal observations

Rabbit No	Group		Interval			
			1h	24h	48h	72h
X1501	Test Article	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Negative Control	Erythema	0	0	0	0
		Oedema	0	0	0	0
X1502	Test Article	Erythema	0	0	0	0
		Oedema	0	0	0	0

	Negative Control	Erythema	0	0	0	0
		Oedema	0	0	0	0
X1503	Test Article	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Negative Control	Erythema	0	0	0	0
		Oedema	0	0	0	0

Under the conditions of this study, the test article did not induce skin irritation in rabbit skin.

11.0 Deviation statement

There was no deviation from the standard operating procedure which were judged to have any impact on the validity of the data.

12.0 Record

All the original data and records related to this test and copies of the final report are retained in the archives of Science Standard Medical Testing.

13.0 Confidentiality agreement

Statements of confidentiality were as agreed upon prior to study initiation.