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Test Report

Report Number: SSMT-R-2020-00803-03

Sample Name: Disposable Medical Mask

Study Title: Skin Sensitization Test - Buehler 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 test article was evaluated for its potential to induce skin sensitization in the test.

Cut the sample into 8 cm^2 pieces and then applied them to ten guinea pigs. Five control animals were treated accordingly but with the negative control.

The topical challenge with the test article excited no skin reaction in the test and in the control animals. The skin sensitization rate was determined with 0%.

Under the conditions of this study, the test article did not show significant evidence of causing skin sensitization in the guinea pig.

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	2020-04-20
Technical Completion Date	2020-05-21
Final Report Completion Date	2020-05-21

Edited by Molly 2020.05.21
Date

Checked by Suri 2020.05.21
Date

Approved by Daisy 2020.06.22
Authorized signatory Date

Jiangsu Science Standard Medical Testing Co., Ltd.

1.0 Purpose

The test was designed to evaluate the potential of test article to cause skin sensitization using Buehler Test in guinea pigs.

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

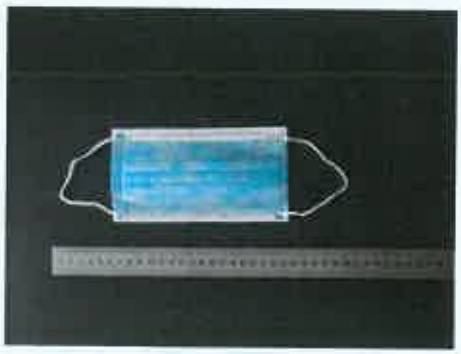
Packing Material: N/S

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: Hartley Guinea Pig

Number: 15 (10 for Test and 5 for Negative Control)

Sex: Males

Initial body weight: 300～500 g

Health status: Healthy, not previously used in other experimental procedures

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

Animal identification: Stain with picric acid

Quarantine: 5 days

5.0 Animal Care and Maintenance

Animal purchase: Provided by Suzhou Genesc Biotechnolongy Co., Ltd. <Permit Code: SCXK (SU) 2015-0002>

Bedding: NA.

Feed: Guinea Pig Diet, Beijing Keao Xieli Feed Co., Ltd.

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

Cages: Plastic cage, Suzhou Fengqiao purification equipment Co., Ltd.

Environment: Temperature 18-29℃, Relative humidity 40%-70%, Lights 12 hours light/dark cycle.

Personnel: Associates involved were appropriately qualified and trained.

Selection: Only healthy, previously unused animals 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 albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study. The susceptibility of the guinea pig to a known sensitizing agent, dinitrochlorobenzene (DNCB) has been substantiated at SSMT. Positive control test is conducted every six months. The last allergenic rate is 100%. The data was from the report SSMT-R-2020-00198-02 (Date: 2020-04-10).

6.2 The test article extract was directly applied to the test system, which is considered to be the best route of administration.

7.0 Equipment

Electronic balance (SSMT-075)

8.0 Experiment design and dose

8.1 Sample preparation

Cut the test sample and the control sample randomly into about 8 cm^2 in size.

8.2 Test method

8.2.1 Induction phase

Apply the prepared test sample patches to the clipped left upper back region of each animal. Remove the occlusive dressings and patches after 6 h. Perform this procedure on three days a week for three weeks. Treat the control animals similarly, using the negative control articles.

8.2.2 Challenge phase

At 13 d after the last induction application, challenge all test and control animals with the test sample. Administer the test sample by a single topical application to a clipped untested area of each animal. Remove the occlusive dressings and patches after 6 h.

8.3 Observation of animal

Observe the appearance of the challenge skin sites of the test and control animals 24 h and 48 h after removal of the dressings. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in Table 1 for each challenge site and at each time interval.

Table 1 Magnusson and Kligman scale

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

9.0 Evaluation criteria

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.

If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.

If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.

10.0 Results of the test

The skin response of guinea pigs is shown in Table 2.

Table 2 Guinea pig Sensitization Dermal Reactions

Group	Animal Number	Excitation patch removed 24 h	Excitation patch removed 48 h	Positive rate after challenge phase	Weight range before injection (g)	Weight range after experiment (g)	Abnormal appearance except dermal reactions
Control	X1001	0	0	0%	326.8-347.8	476.4-519.6	None
	X1002	0	0				None
	X1003	0	0				None
	X1004	0	0				None
	X1005	0	0				None
Test	X2001	0	0	0%	304.5-369.4	451.7-526.4	None
	X2002	0	0				None
	X2003	0	0				None
	X2004	0	0				None
	X2005	0	0				None
	X2006	0	0				None
	X2007	0	0				None
	X2008	0	0				None
	X2009	0	0				None
	X2010	0	0				None

Under the conditions of this study, the test article did not show significant evidence of causing skin sensitization in the guinea pig.

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.