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Sanitation & Environment Technology Institute, Soochow University, Final Report

Report Number: SDWH-M201501556-3

Skin Irritation Test of
Kinesiology Tape
using ISO 10993-10:2010 Test Methods
Topical Application Directly



Sponsor

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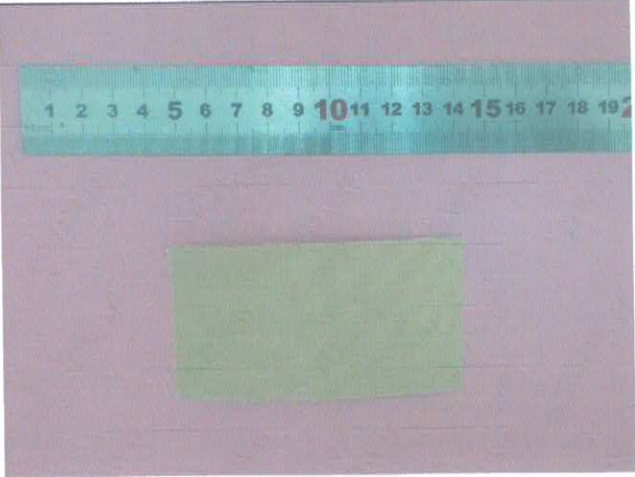
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SUPPLEMENTARY EXPLANATION

1. Please apply for rechecking within 15 days of receiving the report if there are any objections.
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.

STUDY VERIFICATION AND SIGNATURE

Test Article	
Test Article Receipt:	2015-08-03
Protocol No:	SDWH- PROTOCOL-M201501556-3
Protocol Effective Date:	2015-08-03
Technical Initiation Date:	2015-08-07
Technical Completion Date:	2015-08-14
Final Report Completion Date:	2015-08-18

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 2015-08-18
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 2015-08-18
Date

Approved by : Fangbing
Authorized Signatory



Sanitation & Environment Technology Institute, Soochow University

1.0 Summary

The test article Kinesiology Tape was evaluated for skin irritation by contact with the test system directly. The test and control articles were applied to the skin of rabbit, the skin responses on application sites were observed and recorded in (1 ± 0.1) h, (24 ± 2) h, (48 ± 2) h and (72 ± 2) h respectively after removal the patches.

According to what was observed, 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 test article did not induce skin irritation in rabbit under the test condition.

2.0 Purpose

To evaluate the potential skin irritation caused by sample contact with the skin surface of rabbits and extrapolating the results to humans, but it does not establish the actual risk of irritation.

3.0 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)

4.0 Compliance

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (CNAS-CL01 Accreditation Criteria for the competence of testing and calibration laboratories)

China National Accreditation Service for Conformity Assessment

Laboratory Accreditation Certificate No.CNAS L2954

Accreditation Criteria for the competence of the laboratories (Quality and Technical Bureau of Jiangsu Province Metrology Accreditation Certificate CMA 2013100106S)

5.0 Identification of test and control articles

5.1 Test article

Name: Kinesiology Tape

Test Article Initial State: Not sterilized

CAS/Code#: Not supplied by sponsor (N/S)

Size: 5cm*5m

Lot/ Batch#: 201507-1093

Test Article Material: cotton

Packing Material: Shrink Film

Physical State: Solid

Color: Skin

Density: N/S

Stability: N/S

Solubility: N/S

Storage Condition: Room Temperature

The information about the test article was supplied by the sponsor wherever applicable;

5.2 Negative Control

Name: Gauze swabs sterile

Manufacturer: SHAOXING FUQING HEALTH PRODUCTS CO., LTD.

Size: 6cm×8cm-8P

Lot/ Batch#: 20120120
Physical State: solid
Color: white
Storage Condition: Room Temperature

5.3 Positive Control

Name: 20% sodium dodecyl sulfate
Manufacturer: Sinopharm Chemical Reagent Co., Ltd.
Size: 500g
Lot/ Batch#: F20090922
Concentration: 20%
Solvent: 0.9% sodium chloride injection (SC)
Date prepared: 2015-07-07
Physical State: Liquid
Color: Colorless
Storage Condition: Room Temperature

6.0 Identification of test system

Species: New Zealand white Rabbit (single strain).

Number: 3

Sex: Female

Weight: Initial body weight not less than 2kg

Health status: Healthy, not previously used in other experimental procedures, young adult, nulliparous and not pregnant.

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

Animal identification: Stain with picric acid

Cages: Stainless steel cage

Acclimation Period: 7 days under the same conditions as for the actual test

7.0 Animal Care and Maintenance

Animal purchase: Provided by Suzhou Experimental Animal Sci-tech Co., Ltd. <Permit Code: SCXK (SU) 2013-0002>

Bedding: NA

Feed: Rabbit Diet, Suzhou Experimental Animal Sci-tech Co., Ltd.

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

Animal room temperature: 17-25°C

Animal room relative humidity: 30%-70%

Lights: 12 hours light/dark cycle, full-spectrum lighting

Personnel: Associates involved were appropriately qualified and trained.

Selection: Only healthy, previously unused animals were selected.

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

8.0 Justification of the test system

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. Positive control 20% sodium dodecyl sulfate has been substantiated at SDWH with this method.

9.0 Route of administration

Apply the samples of the test article directly to the rabbit skin is considered to be the best means of

contact.

10.0 Experiment design

10.1 Sample and Control Preparation

Aseptically clip the test sample and control sample into 2.5cm×2.5cm.

10.2 Equipment

Electronic Scale (SDWH-442), Calibration Expire (2015-10-22)

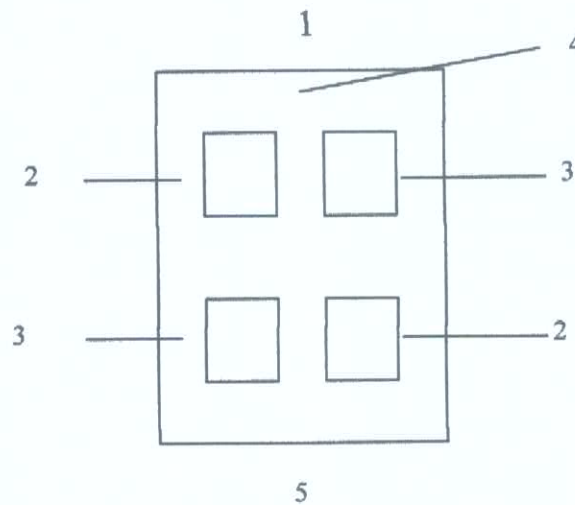
Steel Straight Scale (SDWH-463), Calibration Expire (2015-10-14)

10.3 Reagents

NA

10.4 Experimental Procedure

Use the rabbits with healthy intact skin. Fur is generally clipped within 4-24h of 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 10×15cm).



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

Figure1 Location of skin application sites

Apply the test article (adhesive side for application) directly to the skin on each side of each rabbit as shown in Figure 1. Similarly, apply the control article to each rabbit, and then wrap the application sites with a bandage (semi-occlusive or occlusive) for a minimum of 4h. At the end of the contact time, remove the dressing.

10.5 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 ± 0.1) h, (24 ± 2) h, (48 ± 2) h and (72 ± 2) h following removal of the patches.

Table 1 Classification System for Skin Reaction

Erythema and Eschar Formation:	Numerical Grading
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
Edema Formation:	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Total possible score for irritation	8
Irritation Response Categories in the Rabbit	
Response Category	Mean score
Negligible	0 to 0.4
Slight	0.5 to 1.9
Moderate	2 to 4.9
Severe	5 to 8

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

10.6 Evaluation of results

Use only (24 ± 2) h, (48 ± 2) h and (72 ± 2) h observations for calculation.

After the 72 h grading, all erythema grades plus oedema grades (24 ± 2) h, (48 ± 2) h and (72 ± 2) 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.

When blank or negative control is used, 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.

10.7 Results

According to what observed, the response of skin on testing side does not exceed that on the control side. Thus, the primary irritation index for the test article was calculated to be 0. See table 2.

10.8 Conclusion

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

11.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

12.0 Confidentiality Agreement

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

Table 2 Dermal Observations

Rabbit No	Group		Interval (hours)			
			1	24	48	72
1	Test Article	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Negative Control	Erythema	0	0	0	0
		Oedema	0	0	0	0
2	Test Article	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Negative Control	Erythema	0	0	0	0
		Oedema	0	0	0	0
3	Test Article	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Negative Control	Erythema	0	0	0	0
		Oedema	0	0	0	0

Table 3 Positive control

Rabbit No	Group		Interval (hours)			
			1	24	48	72
1	Positive control	Erythema	2.0	3.5	3.5	4.0
		Oedema	1.5	3.0	2.5	1.5
	Negative Control	Erythema	0	0	0	0
		Oedema	0	0	0	0
2	Positive control	Erythema	1.5	3.0	3.0	3.5
		Oedema	1.5	2.5	2.0	1.0
	Negative Control	Erythema	0	0	0	0
		Oedema	0	0	0	0
3	Positive control	Erythema	1.5	3.0	3.5	3.5
		Oedema	2.0	2.5	1.5	1.5
	Negative Control	Erythema	0	0	0	0
		Oedema	0	0	0	0

Note: Positive control performed once every six months, the positive irritation index was 5.4; see SDWH-M201501241-1(Completed Date: 2015-07-10).