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FINAL REPORT

Study Name: Disposable Medical Face Masks - Skin Irritation Test

Study Number: MED202008586-10-EN

Sponsor

Name: Changzhou Huankang Medical Device Co., Ltd.

Address: 22 Changhe Road, Changzhou, Jiangsu, China

Testing Facility

Name: EPIN Suzhou Ltd.

Address: No.558 Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China

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SUPPLEMENTARY EXPLANATION

1. Please apply for rechecking within 15 days after receiving the report if there is any objection.
2. The report is only valid with the dated signatures by person responsible and cross-page seal.
3. The results in this report relate only to the article tested.
4. The test report shall not be reproduced except in full, without written approval of EPIN Suzhou Ltd.
5. ILAC-G8:09/2019 was employed as the decision rules of statement conformity, where applicable.

TEST ARTICLE CONFIRMATION AND SIGNATURE

Edited by: Eric Zhang Date: 2020-11-05

Eric Zhang (Report Drafter)

Checked by: Look Lu Date: 2020-11-05

Look Lu (Study Director)

Approved by: Juke Wang Date: 2020.11.05

Julie Wang (Authorized Signatory)

TABLE OF CONTENTS

SUMMARY

1. Purpose

To evaluate the potential skin irritation caused by the extraction of the test article extract contacting with the skin surface of rabbits.

2. Process Description

Test article was whole sampled by 3 cm^2: 1 mL, extraction condition was 37℃, 72 h. Extraction solvents were 0.9% sodium chloride (SC) and corn oil (CO).

The rabbits used to conduct experiments were healthy and with intact skin. The fur on the back of the rabbit was clipped within 24 h before the test started, a sufficient area on both sides of the spine for application and observation of all test sites (approximately 10 cm×15 cm). The 2.5 cm×2.5 cm absorbent gauze patches were soaked with 0.5 mL extraction of test article or control and put the patches on the skin on each side of each rabbit directly, then wrapped the test sites with bandage (occlusive) for at least 4 h. At the end of the contact time, removed residual test materials by washing with warm water and made it dry carefully.

Described and scored the skin reactions for erythema and oedema according to the scoring system for each application site at each time interval. Recorded the reaction of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h after removal of the patches.

3. Results

Based on what observed:

The primary irritation index for the test article were calculated to be 0.

No abnormal clinical symptoms except skin reactions was found for all animals.

4. Conclusion

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

1. STUDY SUMMARIES

1.1. Study Name (Study No.)

Disposable Medical Face Masks - Skin Irritation Test (MED202008586-10-EN)

1.2. Purpose

To evaluate the potential skin irritation caused by the extraction of the test article extract contacting with the skin surface of rabbits.

1.3. Referred Standards

- 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

- ISO 10993-2: 2006

  Biological evaluation of medical devices—Part 2: Animal welfare requirements

1.4. Testing Facility

Name: EPIN Suzhou Ltd.

Address: No.558 Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China

1.5. Sponsor

Name: Changzhou Huankang Medical Device Co., Ltd.

Address: 22 Changhe Road, Changzhou, Jiangsu, China

ATTN: Yecheng Zhai

Contact Information: +86 150 2166 5265/519 8890 9800/hk@huankang.com

1.6. Study Alteration Treatment

Before the study start, the study protocol was approved by Study Director and Sponsor. Any study alteration should be approved by Study Director.

1.7. Deviation(s) and Incident(s) Treatment

If any deviation or incident occurred during the test, the related information would be recorded timely and a

deviation report should be submitted with the final report to interpretate the specific effect(s) on the final result caused by the deviation or incident.

1.8. Major Laboratory Personnel(s)

Study Director:	Look Lu
Main Operation Personnel:	Cheery Zhou, Eric Zhang

1.9. Schedule of the Study

Sample Received Date:	2020-08-26
Protocol Effective Date:	2020-09-01
Technical Initiation Date:	2020-10-30
Technical Completion Date:	2020-11-02
Final Report Completion Date:	2020-11-05

2. TEST MATERIAL

2.1. Test Article

2.1.1. General information [1)]

Name:	Disposable Medical Face Masks
Initial State:	Sterile, EO
Size:	175*95mm
Model:	HK-Z01
Lot/ Batch#:	20200820
Physical State:	Solid
Color:	N/S[2)]
Density:	N/S
Stability:	N/S
Solubility:	N/S
Storage Condition:	Room temperature
Test Article Material:	N/S
Packaging Material:	N/S

Manufacturer Name: Changzhou Huankang Medical Device Co., Ltd.

Manufacturer Address: 22 Changhe Road, Changzhou, Jiangsu, China

1) The information about the test article was supplied by the sponsor wherever applicable.
2) N/S means not supplied by the sponsor.

2.1.2. Retention of test article(s)

Retention Volume: 10 pcs

Retention Location: Sample Reserve Room

2.1.3. Handling of residual test article(s)

Tested Article(s): Destroy and waste

Untested Article(s): Destroy and waste

2.2. Negative Control

2.2.1. Polar control information

Name: 0.9% Sodium Chloride (SC)

Size: 500 mL

Lot/ Batch#: B20031901A

Physical State: Liquid

Color: Colorless

Storage Condition: Room Temperature

Manufacturer: Shandong Kelun

2.2.2. Non-polar control information

Name: Corn oil (CO)

Size: 500 mL

Lot/ Batch#: C11094437

Physical State: Pale yellow oily liquid

Storage Condition: Room temperature

Manufacturer: Macklin

2.3. Positive Control

Name:	Sodium Dodecyl Sulfate
Size:	500 g
Lot/ Batch#:	20170712
Physical State:	White powder
Storage Condition:	Room temperature
Manufacturer:	Sinopharm Chemical Reagent Co., Ltd.

2.4. Animal

2.4.1. Animal information

Species:	New Zealand White Rabbit
Microbial Levels:	Conventional
Number/Sex:	6/Female
Weight:	>2kg
Manufacturer:	Zhenhu Experimental Anima Technology Co., Ltd. of Suzhou
Production License#:	SCXK(Su)2020-0007
Quality Certificate#:	No. 202010024

2.4.2. Animal feeding conditions

Breeding Density:	One animal per cage
Cages:	Suspended stainless steel
Animal Identification:	Marked the ID in animal's right ear and identified by a card
Acclimation Period:	At least 7 days under the same conditions as for the actual test
Fodder:	Name: Rabbits maintain feed
	Manufacturer: Beijing Keaoxieli
	Daily 75g quantitative uptake per animal
Water:	Barreled pure water
	Free intake

2.4.3. Animal room environmental conditions

Temperature:	16°C-26°C
Relative Humidity:	40%-70%RH
Ventilation Rate:	≥8/h
Lights:	12 hours light/dark cycle, full spectrum fluorescent lights

2.5. Main Instruments

Name	No.	Calibration Due Date
Electronic Balance	EPB-036	2021-02-24
Shaking Bath	EPB-284	2021-09-28
Clean Bench	EPB-143	2021-02-24

2.6. Justification of the Test System

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. 20% Sodium Dodecyl Sulfate (SDS) is recommended as the positive substance by guiding principle. The recent data of positive control came from MED202006553-10 (Completed Date: 2020-07-06). (See **Attached Table 4-6**).

3. TEST DESIGN

3.1. Test Article Preparation

3.1.1. Extraction process

Sampling Manner	Actual Sampling*	Ratio	Solvent	Amount	Conditions
whole	332.5 cm^2	3 cm^2: 1 mL	SC	110.8 mL	37°C, 72 h
	332.5 cm^2	3 cm^2: 1 mL	CO	110.8 mL	37°C, 72 h

Note: The vehicle (without the test article) was similarly prepared to serve as the negative control.

*: The surface of one test sample is 332.5 cm^2 (provided by the sponsor).

3.1.2. Final extract

Final extract	Additional processing prior to the testing or Not	Presence of particles or Not	Color and Clear or Not
SC	Not	Not	Colorless and Clear

CO	Not	Not	Pale yellow and Clear

Note: Used the final extracts immediately.

3.2. Grouping

Took 6 rabbits into two groups.

Group No.	Group Name	Amount	Sex	Numbered list
1	Test group (SC)	3	♀	1201-1203
2	Test group (CO)	3	♀	2204-2206

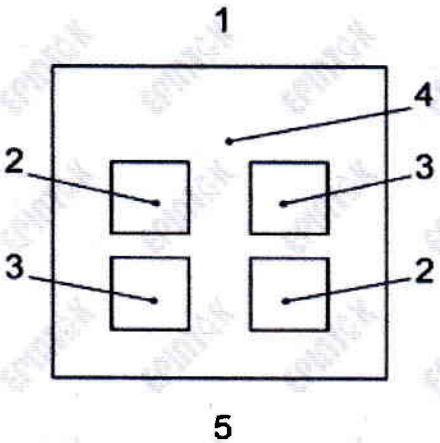
3.3. Experimental Process

3.3.1. Dosing process

Rabbits with healthy and intact skin were used. The fur on the back of the rabbit was clipped within 24 h before the test started, a sufficient area on both sides of the spine for application and observation of all test sites (approximately 10 cm×15 cm).

The 2.5 cm×2.5 cm absorbent gauze patches were soaked with 0.5 mL extract (s) of test article or control and put the patches on the skin on each side of each rabbit directly (See **Figure 1**), and then wrapped the application sites with an occlusive bandage for a minimum of 4 h.

At the end of the contact time, removed the dressings and marked the positions of the sites with permanent ink. Removed residual test material by lukewarm water and careful drying



1. Cranial end 2. Test site 3. Negative control site 4. Clipped dorsal region 5. Caudal end

Figure 1 Location of skin application sites

3.3.2. Observation of animal

Described and scored the skin reaction for erythema and oedema according to the scoring system given in **Table 1** for each application site at each time interval. Recorded 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:	score
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 oedema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	**8**

3.3.3. Other observed endpoints

Clinical symptoms except dermal reactions should be observed every day.

4. EVALUATION CRITERION

Determined the primary irritation index (PII) as follows.

1) Only the data that observed at (24±2) h, (48±2) h and (72±2) h is used for calculation.
2) The erythema grade of every animal at every time point added the oedema grade of every animal at every time point, then the primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).
3) The sum of average grade of all the animals divided by the number of animals.
4) When blank or negative control is used, the primary irritation score was calculated by the average score of test material subtracted the average score of control.

Table 2 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

5. ALTERATION AND DEVIATION

Alteration and deviation did not happen in this study.

6. RESULTS

Based on what observed:

The primary irritation index for the test article were calculated to be 0.

No abnormal clinical symptoms except skin reactions was found for all animals.

7. CONCLUSION

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

8. ARCHIVING

All correspondence, including original copy of the protocol, original copy of the test report, and all raw data generated during the study (i.e., documentation forms as well as any other notes of raw data, printouts of instruments and computers) are stored in the archives room of the EPIN Suzhou Ltd.

9. ATTACHED TABLE

9.1. Attached Table 1 Dermal Observations of Test Group (SC)

Animal No.	Dosing Zone	Skin Reaction	Interval (Hours) 1±0.1	24±2	48±2	72±2	Average Score
1201	Test Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Test Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
	Negative Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
1202	Test Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Test Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
	Negative Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
1203	Test Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Test Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
	Negative Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
The primary irritation index (PII): 0							
Irritation Response Categories: Negligible							

9.2. Attached Table 2 Dermal Observations of Test Group (CO)

Animal No.	Dosing Zone	Skin Reaction	Interval (Hours)				Average Score
			1±0.1	24±2	48±2	72±2	
2204	Test Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Test Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
	Negative Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
2205	Test Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Test Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
	Negative Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
2206	Test Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Test Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
	Negative Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
The primary irritation index (PII): 0							
Irritation Response Categories: Negligible							

9.3. Attached Table 3 Body Weight and Clinical Observation

Animal No.	Body Weight (g)		Clinical Observation
	Initiation	End	
1201	2859	2974	Normal
1202	2718	2838	Normal
1203	2467	2588	Normal
2204	2344	2486	Normal
2205	2302	2443	Normal
2206	2623	2718	Normal

9.4. Attached Table 4 Dermal Observations of Positive Group

Animal No.	Dosing zone	Skin Reaction	Interval (hours) 1±0.1	24±2	48±2	72±2	Average score
5207	Positive Site (Left)	Erythema	0	3	3	3	6
		Oedema	2	3	3	3	
	Positive Site (Right)	Erythema	0	3	3	3	
		Oedema	2	3	3	3	
	Negative Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
5208	Positive Site (Left)	Erythema	0	3	3	3	6
		Oedema	2	3	3	3	
	Positive Site (Right)	Erythema	0	3	3	3	
		Oedema	2	3	3	3	
	Negative Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
5209	Positive Site (Left)	Erythema	0	3	3	3	6
		Oedema	2	3	3	3	
	Positive Site (Right)	Erythema	0	3	3	3	
		Oedema	2	3	3	3	
	Negative Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
The primary irritation index (PII): 6							
Irritation Response Categories: Severe							

Note: The recent data of positive control came from MED202006553-10 (Completed Date: 2020-07-06).

9.5. Attached Table 5 Dermal Observations of Positive Group

Animal No.	Dosing zone	Skin Reaction	Interval (hours) 1±0,1	24±2	48±2	72±2	Average score
6210	Positive Site (Left)	Erythema	0	3	3	3	6
		Oedema	2	3	3	3	
	Positive Site (Right)	Erythema	0	3	3	3	
		Oedema	2	3	3	3	
	Negative Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
6211	Positive Site (Left)	Erythema	0	3	3	3	6
		Oedema	2	3	3	3	
	Positive Site (Right)	Erythema	0	3	3	3	
		Oedema	2	3	3	3	
	Negative Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
6212	Positive Site (Left)	Erythema	0	3	3	3	6
		Oedema	2	3	3	3	
	Positive Site (Right)	Erythema	0	3	3	3	
		Oedema	2	3	3	3	
	Negative Site (Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site (Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
The primary irritation index (PII): 6							
Irritation Response Categories: Severe							

Note: The recent data of positive control came from MED202006553-10 (Completed Date: 2020-07-06).

9.6. Attached Table 6 Body Weight and Clinical Observation of Positive Group

Animal No.	Body Weight (g)		Clinical Observation
	Initiation	End	
5207	2393	2481	Normal
5208	2812	2909	Normal
5209	2135	2221	Normal
6210	2422	2511	Normal
6211	2760	2856	Normal
6212	2573	2666	Normal

Note: The recent data of positive control came from MED202006553-10 (Completed Date: 2020-07-06).

End of Report