Test Report

Date : 2021-06-25
No. : HC21040678

Applicant(Code:01325334): Art Beauty Group Company Limited
Unit 2305 Apec Plaza
43 Hoi Yuen Road
Kwun Tong Kln HK

Description of Sample(s) : One submitted sample said to be Surgical Face Mask.
Country of Origin : Taiwan

Sample Receiving Condition: In plastic bag under ambient temperature

Date Sample(s) Received : 2021-04-21

Date Tested : 2021-04-25 to 2021-05-28

Investigation Requested : Primary Skin Irritation Study in Rabbits

CHUNG On Ping, Karen
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

The Hong Kong Standards and Testing Centre Limited
10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong
Tel: +852 2666 1888 Fax: +852 2664 4353 Email: hkstc@stc.group Website: www.stc.group

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Summary

The test article, Surgical Face Mask, was evaluated for primary skin irritation in rabbits. This study was conducted based on the requirements of ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. The test articles were extracted in 0.9% sodium chloride injection and Soybean oil. Two 25 mm x 25 mm sections of absorbent gauze patches with 0.5ml test extracts/ control extracts were topically applied to the skin of each of three rabbits and left in place for 4 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single application.

There was no erythema and no edema observed on the skin of the animals treated with the test extracts. The Primary Irritation Index for the test extracts was calculated to be 0.0. The response of the test article was categorized as negligible.

1. Introduction

1.1 Purpose

The purpose of this study was to evaluate the test article for the potential to cause skin irritation in rabbit.

1.2 Testing Guidelines

This study was based on the requirements of the International Organization for Standardization 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

1.3 Dates

Test Article Received:	2021.04.25
Test Started:	2021.05.22
Observations Concluded:	2021.05.28

2. Identification of Test and Control Articles

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

Table 1 - Test Article

Name	Surgical Face Mask
Size	175mm×95mm
CAS:	N.A.
Model	N.A.
Lot	N.A.
Initial State	Not Sterilized
Strength, Purity and Composition	1st Layer: PP; 2nd Layer: Mel Blown; 3rd Layer: PP
Color	Blue
Physical Description of the Test Article	Solid
Manufacture Date	N.A.
Expiration Date	N.A.

Table 2 - Negative Control Article

Name	Sodium chloride injection (SC) Soybean oil (SO)
Purity, Composition, and Other Characteristics:	SC: Composition: 0.9% NaCl ± 5.0% of label claim, balance is water; sodium chloride CAS No.: 7647-14-5/water CAS No.: 7732-18-5 SO: Composition: CAS No.: 8001-22-7

Table 3 - Reagents

Name	Brand	Lot
SC	Jiangxikelun	C20092904
SO	Tianyushan	20201201

3. Test System

3.1 Test System

Species:	Rabbit (Oryctolagus cuniculus)
Strain:	New Zealand White
Source:	Guangzhou Huadu Xinhua Animal Farm
Sex:	Male & Female (Females were nulliparous and nonpregnant)
Age:	Young adult
Acclimation Period:	Minimum 5 days
Number of Animals:	6
Identification Method:	Name card

3.2 Test System management

The rabbit (animal) is specified as an appropriate animal model for evaluating potential skin irritants by the current ISO testing standards. The rabbit is widely used for this purpose and relative ranking of irritant scores can be determined.

4. Animal Management

4.1 Husbandry, Housing and Environment

Conditions conformed to STC Standard Operating Procedures. Animals were housed in groups in stainless steel or plastic suspended cages identified by a card indicating the animal numbers, test code, sex, animal code and date dosed.

The animal housing room is conventional system lab. The lab animal using license : SYXK(Guangdong Province)2019-0159. The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 19-26°C and the relative humidity was set to 40-70%. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals.

The light cycle was controlled (12 hours light, 12 hours dark).

4.2 Food, Water and Contaminants

Food: Laboratory animal formula feed (rabbit), Shenyang maohua biotechnology co. LTD, was provided daily.

Water: The water quality met the "Sanitary standard for drinking water" (GB5749-2006)

Food and water were sterile. No contaminants present in the feed and water impacted the results of this study.

4.3 Personnel

Associates involved in this study were appropriately qualified and trained.

4.4 Veterinary Care

Standard veterinary medical care was provided in this study.

4.5 IACUC

This procedure has been approved by the STC Institutional Animal Care and Use Committee (IACUC), and is reviewed at least annually by the same committee.

4.6 Selection

Only healthy, animals free from irritation or other dermatological lesions that could interfere with the test were selected.

5. Method

5.1 Test and Control Article Preparation

The preparations of the test article and the negative control were subjected to the extraction conditions as described below. The extracts were continuously agitated during extraction.

Table 4 - Extraction

Vehicle	Treatment Group	Extraction Ratio	Article Amount	Volume of Vehicle	Extraction Condition
SC	Test	3 cm^2/mL	332.5 cm^2	110.8 mL	50±2°C for 72±2 h
	Control	N. A	N. A	20 mL	
SO	Test	3 cm^2/mL	332.5 cm^2	110.8 mL	
	Control	N. A	N. A	20 mL	

The following table contains a description of the test and control article extracts before and after extraction.

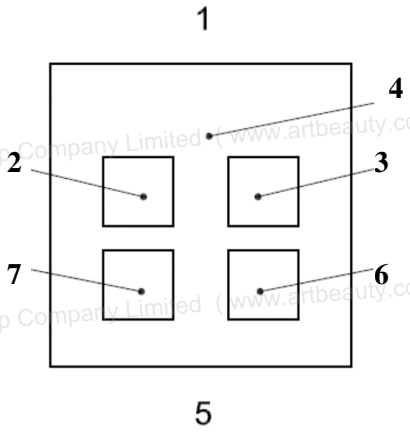
Table 5 - Condition of Extracts

Vehicle	Time Observed	Extract	Condition of Extracts		
			Color	Clarity	Particulates
SC	Before Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	After Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	Prior to Use	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
SO	Before Extraction	Test	Colorless	Oily	None
		Control	Colorless	Oily	None
	After Extraction	Test	Colorless	Oily	None
		Control	Colorless	Oily	None
	Prior to Use	Test	Colorless	Oily	None
		Control	Colorless	Oily	None

The test article extracted in SC and SO remained unchanged during the extraction process. The extracts were maintained at ambient temperature <24 hours before use for all phases. The extracts were not centrifuged, filtered, or otherwise altered prior to dosing.

5.2 Test Procedure

The animals were weighed and the fur on the back of each animal was clipped with an electric clipper 24 hours prior to treatment. On the day of treatment, four sites, two on each side of the back and positioned cranially and caudally, were designated on each animal. The sites were free of blemishes that could interfere with the interpretation of results. The appropriate extracts were applied to the 2.5 cm × 2.5 cm absorbent gauze patches. 0.5 ml extract was used to saturate the gauze. A control patch of gauze moistened with the extract vehicle was applied as well. And then all the application sites were covered with a bandage (semi-occlusive or occlusive) for a minimum of 4 h. Animals were returned to their cages after treatment. After the 4-hour exposure, the binders, tape, and patches were removed. The sites were gently wiped with a gauze sponge dampened with deionized water in an attempt to remove any remaining residue.



1 – Cranial end 2 – Test site 3 – Control site 4 – Clipped dorsal region
5 – Caudal end 6 – Test site 7 – Control site

5.2.1 Laboratory Observations

1. Animals were observed daily for general health.
2. Body weights were recorded for each animal at pretreatment.
3. Dermal observations for erythema and edema were recorded at 1, 24, 48 and 72 hours after patch removal in accordance with the criteria in Appendix 1.

Table 6 Classification System for Skin Reaction

Erythema and Eschar Formation	Numerical Grading	Edema Formation	Numerical Grading
No erythema	0	No edema	0
Very slight erythema (barely perceptible)	1	Very slight edema (barely perceptible)	1
Well-defined erythema	2	Well-defined edema (edges of area well-defined by definite raising)	2
Moderate erythema	3	Moderate edema (raised approximately 1 mm)	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4	Severe edema (raised more than 1 mm and extending beyond exposure area)	4
Total possible score for irritation			8

Table 7 Irritation Response Categories in the Rabbit

Irritation Response Categories in the Rabbit	
Response Category	Mean Score
Negligible	0-0.4
Slight	0.5-1.9
Moderate	2.0-4.9
Severe	5-8

All times and temperatures reported here in are approximate and are within ranges established by the external standards described in the References section of this report and/or STC standard operating procedures.

6. Evaluation

The Primary Irritation Index of the test was calculated following test completion for each animal. The erythema and edema scores obtained at the 24, 48 and 72-hour intervals were added together and divided by the total number of observations. This calculation was conducted separately for the test and control article for each animal. The score for the control was subtracted from the score for the test article to obtain the Primary Irritation Score. The Primary Irritation Score for each animal was added together and divided by the number of animals to obtain the Primary Irritation Index. The Primary Irritation Index was characterized based on the definitions.

7. Results

All the animals were clinically normal throughout the study. Individual results of dermal scoring are presented in Appendix 1. No irritation was observed on the skin of the animals. The Primary Irritation Index of the test article was calculated to be 0.0. The irritation calculations are shown below:

Table 8 Irritation Calculations of SC Group

Animal Number	Test Score Average	Control Score Average	Individual Primary Irritation Score	Combined Primary Irritation Score (CPIS)	Primary Irritation Index (CPIS/3)	Response Category
2021021801	0	0	0	0	0	Negligible
2021042901	0	0	0			
2021042903	0	0	0			

Table 9 Irritation Calculations of SO Group

Animal Number	Test Score Average	Control Score Average	Individual Primary Irritation Score	Combined Primary Irritation Score (CPIS)	Primary Irritation Index (CPIS/3)	Response Category
2021042904	0	0	0	0	0	Negligible
2021042905	0	0	0			
2021042906	0	0	0			

8. Conclusion

There was no erythema and no edema observed on the skin of the animals treated with the test article. The Primary Irritation Indexes for the test article extracts were both calculated to be 0.0. The response of the test article extracts was categorized as negligible.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

9. Records

All raw data pertaining to this study and a copy of the final report are retained in designated STC archive files in accordance with STC SOPs.

10. ISO Compliance

All procedures were compliance to ISO 17025.

11. References

Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process (2018).

International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices -Part 2: Animal welfare requirements (2006).

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

International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices -Part 12: Sample preparation and reference materials (2012).

International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, General requirements for the competence of testing and calibration laboratories (2017).

Appendix 1 – Dermal Observations

Table 10 Dermal Observations of SC Group

Animal number	Weight (g)	Group	Observation	Interval (hours)			
				1	24	48	72
2021021801	4271.9	Test	Erythema	0	0	0	0
			Edema	0	0	0	0
		Control	Erythema	0	0	0	0
			Edema	0	0	0	0
2021042901	2826.6	Test	Erythema	0	0	0	0
			Edema	0	0	0	0
		Control	Erythema	0	0	0	0
			Edema	0	0	0	0
2021042903	3144.5	Test	Erythema	0	0	0	0
			Edema	0	0	0	0
		Control	Erythema	0	0	0	0
			Edema	0	0	0	0

Table 11 Dermal Observations of SO Group

Animal number	Weight (g)	Group	Observation	Interval (hours)			
				1	24	48	72
20210429 04	2987.3	Test	Erythema	0	0	0	0
			Edema	0	0	0	0
		Control	Erythema	0	0	0	0
			Edema	0	0	0	0
20210429 05	2549.4	Test	Erythema	0	0	0	0
			Edema	0	0	0	0
		Control	Erythema	0	0	0	0
			Edema	0	0	0	0
20210429 06	3117.5	Test	Erythema	0	0	0	0
			Edema	0	0	0	0
		Control	Erythema	0	0	0	0
			Edema	0	0	0	0

Appendix 2 – Periodic Positive Control Study for Primary Skin Irritation Test

What was tested
sodium dodecyl sulfate (SDS)

Dates
Treatment Started: 2021.02.21
Observations Concluded: 2021.02.24

Purpose：
A periodic positive control study was conducted for the Primary Skin Irritation Test to meet the following objectives: 1) confirm the methodology in ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization, 2) substantiate the potential of SDS to cause irritant effects, 3) verify proper training of the technicians performing these studies, and 4) substantiate the susceptibility of the rabbit strain to primary skin irritation test.

Methods：
The test utilized young adult, 2 female rabbits (nulliparous and not pregnant) & 1 male rabbit supplied by Guangzhou baiyun district longgui xingke animal farm. The weight at study initiation ranged from 2kg to 4kg. Two 25 mm x 25 mm sections of absorbent gauze patches with 0.5ml 20% (w/w) concentration of SDS was topically applied to the skin of each of three rabbits and left in place for 4 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single application.

Results：
All the three sites demonstrated a positive skin irritation to the known skin irritant, SDS. None of the control sites of animals demonstrated an irritation response. The Irritation Calculations are shown below:

Animal Number	Test Score Average	Control Score Average	Individual Primary Irritation Score	Combined Primary Irritation Score (CPIS)	Primary Irritation Index (CPIS/3)	Response Category
2020111203	8	0	8	24	8	Severe
2020111207	8	0	8			
2020111216	8	0	8			

Conclusion

The known skin irritant SDS produced evidence of causing primary skin irritation in the New Zealand White strain of rabbit. Therefore, the following objectives were met: 1) the methodology in ISO 10993-10:2010, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization was confirmed, 2) the potential for SDS to cause skin irritation was substantiated, 3) proper training of the technicians performing this study design was verified and 4) the susceptibility of the New Zealand White rabbit strain to skin irritation was substantiated.