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检测
TESTING
CNAS L13034

Skin Irritation Test

Extraction Method

Final Report

Verification

Report Number: CSTBB2022020078

Article Name: 3DMASK

Method Standard: ISO 10993-10: 2010

Sponsor

Savewo Limited

Hong Kong, China

Test Facility

CCIC Huatongwei International Inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

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Notices

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 report is only responsible for the test results of the tested samples.
5. The report shall not be reproduced except in full without the written approval of the company.
6. ISO 10993-2:2006 and ISO 10993-12:2021 are not within the scope of qualification.

Abstract

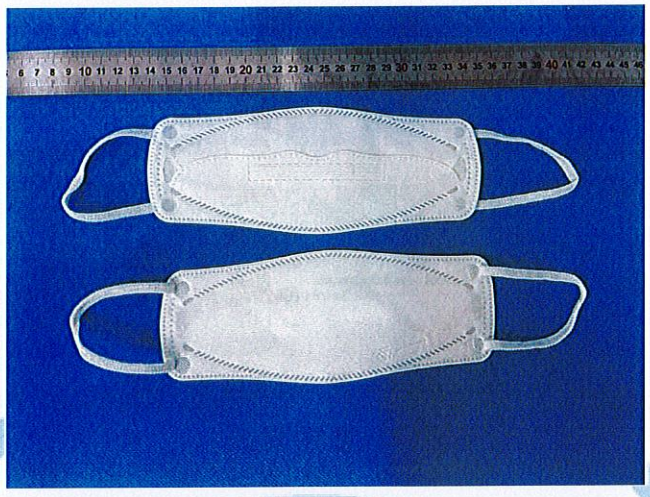
In this study, we took New Zealand white Rabbits to observe the skin irritation of the test article according to ISO 10993-10:2010.

The test article were extracted by 0.9 % Sodium Chloride Injection and Sesame Oil. Apply 0.5 ml extracts of test article or control to 2.5 cm×2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit, and then wrap the application sites with a bandage for a minimum of 4 h. At the end of the contact time, remove the dressing. The describe and score the skin reaction for erythema and oedema 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.

The results showed that the rabbits in the negative control group (0.9 % Sodium Chloride Injection, Sesame Oil) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (SDS). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article has no skin irritation on rabbits.

Study Verification and Signature



Protocol Number	SST2201001404BB
Protocol Effective Date	2022-01-07
Technical Initiation Date	2022-01-07
Technical Completion Date	2022-01-14
Final Report Completion Date	2022-02-18

Personnel — Betty Zhuang — 2022-02-18 (Date Completed)

Approved — Hongtia Li (Study Director) — 2022-02-18 (Date Completed)

Supervisory — Suzhou (Test Facility Manager) — 2022-02-18 (Date Completed)

CCIC Huatongwei International Inspection (Suzhou) Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the HTW's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase Inspected	Date	Study Director	Management
Experiment	2022-01-07	2022-01-07	2022-01-07
Raw Data	2022-01-14	2022-01-14	2022-01-14
Final Report	2022-02-18	2022-02-18	2022-02-18

The findings of these inspections have been reported to Management and the Study Director.

Quality Assurance　　2022-02-18 Date

GLP Statement

This study was conducted in compliance with current U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of HTW, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Hongtia Li
Study Director

2022-02-18
Date

1.0 Purpose

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

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 2: Animal welfare requirements (ISO 10993-2:2006)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2021)

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	3DMASK	0.9% Sodium Chloride Injection(SC)	Sesame Oil (SO)	Sodium dodecyl sulfate (SDS)
Manufacturer	Savewo Limited	Guangxi Yuyuan Pharmaceutical Co., Ltd	Zhejiang Tianyu yam Oil Co., Ltd	Solarbio
Size	208mm X 81mm	500 ml	1L	500 g
Model	Not Provided	/	/	/
Lot Batch#	Not Provided	H21011707	MX20210401	1019Y032
Test Article Material	polypropylene non-woven fabric, polypropylene melt-blown fabric, Nylon + Spandex Earloop, Polyethylene plastic + Aluminium Wire, Nose Strip	/	/	/
Physical State	Not Provided	Liquid	Liquid	Solid
Color	(Red Straps)	Colorless	Light yellow	White
Package material	PE and paper	/	/	/
Sterilized or Not	Not Sterilized	/	/	/
Concentration	/	0.9 %	/	working concentration 10 %

Surface (cm^2)	Not Provided	/	/	/
Weight (g)	Not Provided	/	/	/
Storage Condition	Room Temp.	Room Temp.	Room Temp.	Room Temp.
The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification of test system

4.1 Test animal

Species: New Zealand white Rabbit

Number: 6

Sex: either sex

Weight: >2 kg

Health status: Healthy, not previously used in other experimental procedures. Female animals were nul liparous and not pregnant.

Animal identification: Ear tattoo

Cages: Stainless steel cage

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

4.2 Justification of test system

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the c urrent testing standards. Positive control 10% sodium dodecyl sulfate has been substantiated at HTW with this method.

5.0 Animal management

Animal purchase: Wuxi hengtai experimental animal breeding co. LTD SCXK (SU) 2020-0003

Feed: Experimental rabbits were fed a maintenance diet, Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

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

Animal room temperature: 18-26 ℃

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, or bedding expected to interfere with the test data

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2021/03/11), Electronic scale (SHB020, calibration data: 2021/03/11)

7.0 Experiment design

7.1 Sample preparation

The extracts of test article will be prepared according to the following steps:

Aseptic Sampling		Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Reagent		Condition	pH
Whole	731.0 cm^2	6 cm^2: 1 ml	SC	121.8 ml	50 ℃ / 72 h/ 60rpm	5.5
	731.0 cm^2		SO	121.8 ml		/

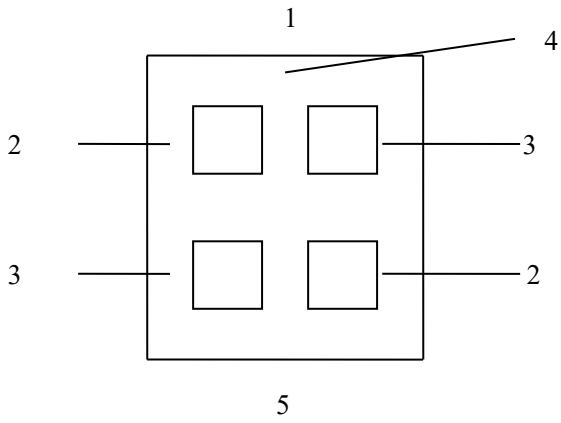
Both induction and challenge phase extracts were prepared by the number of times. The state of the leaching solution did not change visually after the leaching was advanced.The control solution was prepared under the same conditions.The extraction of the test article could be stored at room temperature for no more than 24 h. No particulates or color changes were observed in pre- and post-extraction, the color and pH of the extraction solution did not change before and after use,and the pH value was 5.5, the status of the extract was shown in the table below.

Vehicle	Time Observed	Extracts	Condition of Final Extracts		
			Color	Clear or Not	Particulates
0.9% Sodium Chloride Injection(SC)	Before Extraction	Test article	Colorless	Clear	None
		Negative Control	Colorless	Clear	None
	After Extraction	Test article	Colorless	Clear	None
		Negative Control	Colorless	Clear	None
Sesame Oil (SO)	Before Extraction	Test article	Light yellow	Clear	None
		Negative Control	Light yellow	Clear	None
	After Extraction	Test article	Light yellow	Clear	None
		Negative Control	Light yellow	Clear	None

7.2 Test method

Use the rabbits with healthy intact skin. Fur was generally clipped within 24 h period 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 0.5 ml extract (s) of test article or control to 2.5 cm×2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit as shown in Figure 1, 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.



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

Figure1 Location of skin application sites

8.0 The results observed

The 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
Maximal 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

9.0 Evaluation criteria

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 were totalled separately for each test article and blank for each animal. 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).

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

When blank or negative control was 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.

10.0 Results of the test

All animals were survived and no abnormal signs were observed during the study. According to what observed, the response of skin on testing side did not exceed that on the control side. Thus, the primary irritation index for the test article was calculated to be 0. See table 2.

11.0 Conclusion

Based on the above results, it can be concluded that under the experimental conditions, the test article has no skin irritation on rabbits. Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor’s responsibility.

12.0 Compliance

US FDA Good Laboratory Practice Regulations 21 CFR 58, effective June 20, 1979, as amended 52 FR 33780, Sept. 4, 1987, and subsequent amendments

Standard operating procedure of CCIC Huatongwei International Inspection (Suzhou) Co., Ltd.

13.0 Record

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

14.0 Confidentiality agreement

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

15.0 Protocol amendment/deviations

There were no amendments or deviations that occurred during the course of this study.

Table 2 Skin irritation response observation

Reagent	Rabbit No.	Pretest weight(kg)	Finished weight(kg)	Group	Reaction	Interval (hours): score=left/right			
						1±0.1h	24±2 h	48±2 h	72±2 h
SC	1	2.09	2.20	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	2	2.12	2.23	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	3	2.14	2.25	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
Primary irritation index						0			
SO	4	2.17	2.28	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	5	2.21	2.32	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	6	2.13	2.24	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
Primary irritation index						0			

Table 3 Positive control

Rabbit No.	Group	Reaction	Interval (hours): score=left site/right site			
			1±0.1 h	24±2 h	48±2 h	72±2 h
1	Positive Article Group	Erythema	1/1	2/3	2/3	3/4
		Oedema	0/1	2/2	3/3	4/4
	Solution Control Group	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
2	Positive Article Group	Erythema	0/1	1/2	2/3	3/3
		Oedema	0/0	2/2	3/3	4/3
	Solution Control Group	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
3	Positive Article Group	Erythema	0/1	1/2	3/3	4/4
		Oedema	0/0	2/1	3/4	3/4
	Solution Control Group	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
Primary irritation index			5.6			

Positive control performed once every six months see CSTBB21120002P1(Finish date：2021-12-10)

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TESTING
CNAS L13034

Skin Sensitization Test

Guinea Pig Maximization

Final Report

Verification

Report Number: CSTBB2022020077

Article Name: 3DMASK

Method Standard: ISO 10993-10: 2010

Sponsor

Savewo Limited

Hong Kong, China

Test Facility

CCIC Huatongwei International Inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

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6. ISO 10993-2:2006 and ISO 10993-12:2021 are not within the scope of qualification.

Abstract

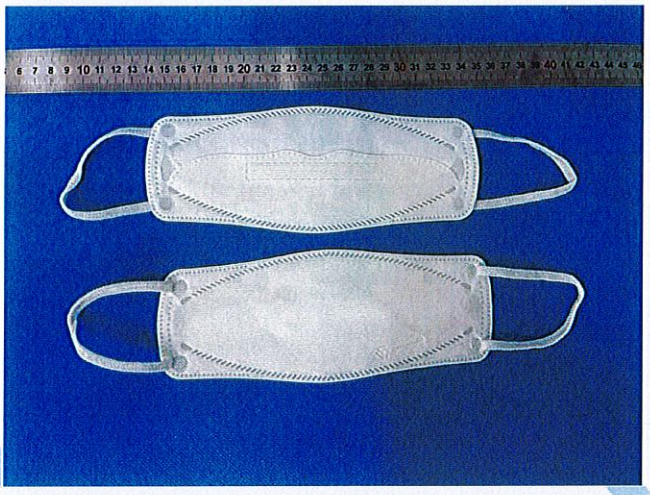
In this study, we took guinea pigs to observe the skin sensitization of the test article according to ISO 10993-10: 2010.

The test article were extracted by 0.9% Sodium Chloride Injection and Sesame Oil. The extract was mixed with Fresch's complete adjuvant into a stable emulsifier. Intradermal induction and topical induction were operated in the clipped intrascapular region of each animal. At 14d after completion of the topical induction phase, Challenge all test and control animals with the test sample at sites that were not treated during topical induction phase. The erythema and edema of the challenge site were observed to test the sensitization response of the test article. According to the Magnusson and Kligman scales, the response to erythema and edema at each application site of the skin was described and scored 24 hours and 48 hours after the challenge phase.

The results showed that the guinea pigs in the negative control group (0.9% Sodium Chloride Injection, Sesame Oil) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (DNCB). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article has no potential skin sensitization on guinea pigs in the extraction method.

Study Verification and Signature



Protocol Number	SST2201001403BB
Protocol Effective Date	2022-01-07
Technical Initiation Date	2022-01-07
Technical Completion Date	2022-02-04
Final Report Completion Date	2022-02-18

Personnel Berry Zhuang 2022-02-18
Date Completed

Approved Hongxia Li 2022-02-18
Study Director Date Completed

Supervisory
Test Facility Manager 2022-02-18
Date Completed

CCIC Huatongwei International Inspection (Suzhou) Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the HTW's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase Inspected	Date	Study Director	Management
Experiment	2022-01-07	2022-01-07	2022-01-07
Raw Data	2022-02-04	2022-02-04	2022-02-04
Final Report	2022-02-18	2022-02-18	2022-02-18

The findings of these inspections have been reported to Management and the Study Director.

Hui Tang
Quality Assurance

2022-02-18
Date

GLP Statement

This study was conducted in compliance with current U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of HTW, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Hongtia Li
Study Director

2022-02-18
Date

1.0 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

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 2: Animal welfare requirements (ISO 10993-2:2006)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2021)

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	3DMASK	0.9% Sodium Chloride Injection(SC)	Sesame Oil (SO)	2, 4-Dinitrochlorobenzene (DNCB)
Manufacturer	Savewo Limited	Guangxi Yuyuan Pharmaceutical Co., Ltd	Zhejiang Tianyu yam Oil Co., Ltd	TOKYO CHEMICAL INDUSTRY CO., LTD
Size	208mm X 81mm	500 ml	1L	25 g
Model	Not Provided	/	/	/
Lot Batch#	Not Provided	H21011707	MX20210401	H2UKD-DM
Test Article Material	polypropylene non-woven fabric, polypropylene melt-blown fabric, Nylon + Spandex Earloop, Polyethylene plastic + Aluminium Wire, Nose Strip	/	/	/
Physical State	Not Provided	Liquid	Liquid	Solid
Color	(Red Straps)	Colorless	Light yellow	Light yellow
Package material	PE and paper	/	/	/
Sterilized or Not	Not Sterilized	/	/	/
Concentration	/	0.9 %	/	Induction Concentration:

				0.1 % Challenge Concentration: 0.05 % Dissolved in ethanol
Surface (cm^2)	Not Provided	/	/	/
Weight (g)	Not Provided	/	/	/
Storage Condition	Room Temp.	Room Temp.	Room Temp.	Room Temp.
The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification of test system

4.1 Test animal

Species: Hartley Guinea Pig (Cavia Porcellus)

Number: 30 (20 Test +10 Control)

Sex: either sex

Initial body weight: 300.0~500.0 g

Health status: Healthy, not previously used in other experimental procedures. Female animals were nul liparous and not pregnant.

Animal identification: Ear tag

Cages: Plastic cage

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

4.2 Justification of test system

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1 970). The guinea pig is believed to be the most sensitive animal model for this type of study. DNCB is the positive control article recommended in the test instructions. To ensure the sensitivity of the experime ntal system, the positive control article should be verified every three months.

5.0 Animal management

Animal purchase: Wuxi hengtai experimental animal breeding co. LTD SCXK (SU) 2020-0003

Bedding: Corncob Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Feed: Guinea pigs were fed with full-price pellets Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

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

Animal room temperature: 18-26 ℃

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, or bedding expected to interfere with the test data.

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2021/03/11), Electronic scale (SHB017, calibration data: 2021/03/11)

6.2 Reagents

Freund’s adjuvant Complete liquid (SIGMA, Lot No: SLCC3348), Sodium dodecyl sulfate (Solarbio, Lot No: 1019Y032)

7.0 Experiment design

7.1 Sample preparation

The extracts of test article will be prepared according to the following steps:

Aseptic Sampling			Extraction in sterile vessels				
	Sampling Manner	Actually sampling	Ratio	Reagent		Condition	pH
Intradermal induction phase I	Whole	731.0 cm^2	6 cm^2: 1 ml	SC	121.8 ml	50 ℃ / 72 h/ 60rpm	5.5
		731.0 cm^2		SO	121.8 ml		/
Topical induction phaseII	Whole	731.0 cm^2	6 cm^2: 1 ml	SC	121.8 ml	50 ℃ / 72 h/ 60rpm	5.5
		731.0 cm^2		SO	121.8 ml		/
Challenge phase	Whole	731.0 cm^2	6 cm^2: 1 ml	SC	121.8 ml	50 ℃ / 72 h/ 60rpm	5.5
		731.0 cm^2		SO	121.8 ml		/

Both induction and challenge phase extracts were prepared by the number of times. The state of the leaching solution did not change visually after the leaching was advanced. The control solution was prepared under the same conditions.The extraction of the test article could be stored at room temperature. for no more than 24 h. No particulates or color changes were observed in pre- and post-extraction, the color and pH of the extraction solution did not change before and after use,and the pH value was 5.5, the status of the extract was shown in the table below.

Phase	Vehicle	Time Observed	Extracts	Condition of Final Extracts		
				Color	Clear or Not	Particulates
Intradermal induction phase I	0.9% Sodium Chloride Injection(SC)	Before Extraction	Test article	Colorless	Clear	None
			Negative Control	Colorless	Clear	None
		After Extraction	Test article	Colorless	Clear	None
			Negative Control	Colorless	Clear	None
	Sesame Oil (SO)	Before Extraction	Test article	Light yellow	Clear	None
			Negative Control	Light yellow	Clear	None
		After	Test article	Light yellow	Clear	None

		Extraction	Negative Control	Light yellow	Clear	None
Topical induction phaseII	0.9% Sodium Chloride Injection(SC)	Before Extraction	Test article	Colorless	Clear	None
			Negative Control	Colorless	Clear	None
		After Extraction	Test article	Colorless	Clear	None
			Negative Control	Colorless	Clear	None
	Sesame Oil (SO)	Before Extraction	Test article	Light yellow	Clear	None
			Negative Control	Light yellow	Clear	None
		After Extraction	Test article	Light yellow	Clear	None
			Negative Control	Light yellow	Clear	None
Challenge phase	0.9% Sodium Chloride Injection(SC)	Before Extraction	Test article	Colorless	Clear	None
			Negative Control	Colorless	Clear	None
		After Extraction	Test article	Colorless	Clear	None
			Negative Control	Colorless	Clear	None
	Sesame Oil (SO)	Before Extraction	Test article	Light yellow	Clear	None
			Negative Control	Light yellow	Clear	None
		After Extraction	Test article	Light yellow	Clear	None
			Negative Control	Light yellow	Clear	None

7.2 Test method

7.2.1 Intradermal induction phaseI

Make a pair of 0.1 ml intradermal injections of each of the following, into each animal, at the injection sites (A, B and C) , as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 volume ratio stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.

Site B: The test sample (undiluted extract); inject the control animals with the extraction solvent alone.

Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent; inject the control animals with an emulsion of the blank liquid with adjuvant.

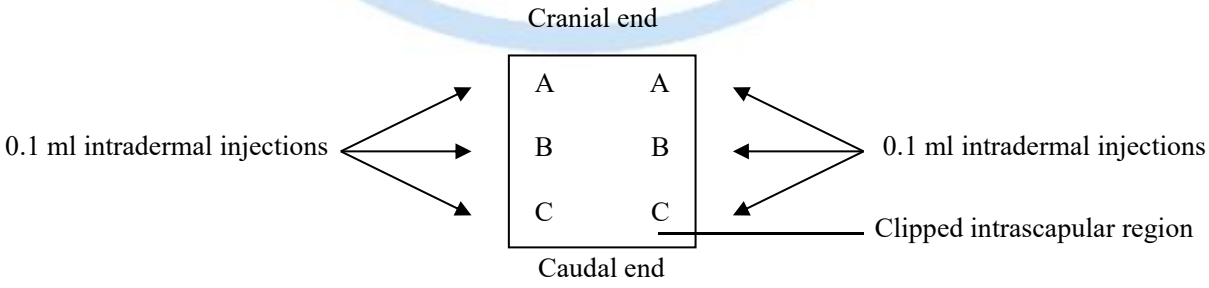


Figure 1 Location of intradermal injection sites

7.2.2 Topical induction phaseII

At (7±1) d after the intradermal induction phase, administer the test article extract by topical application to the intrascapular region of each animal, using a patch of area approximately 8cm^2 (absorbent gauze), so as to cover the

intradermal injection sites. If the maximum concentration that can be achieved in Intradermal induction phase I does not produce irritation, pretreat the area with 10% sodium dodecyl sulfate(SDS) massaged into the skin (24±2) h before the patch is applied. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48±2) h.

Treat the control animals similarly, using the blank liquid alone.

7.2.3 Challenge phase

All test and control animals shall be challenged at 14 d after completion of the topical induction phase. Absorbent gauzes (2.5 cm x 2.5 cm) were soaked respectively with test article and control article. Apply the test article extract and control article topically to two sites that were not treated during the induction stage. The patches shall be secured with an occlusive dressing. Dressings and patches shall be removed after (24±2) h.

8.0 The results observed

Observe the appearance of the challenge skin sites of the test and control animals (24±2) h and (48±2) h after removal of the dressings. Use of natural lighting is highly recommended in order to visualize the skin reactions. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading scale 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. The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

10.0 Results of the test

All animals were survived and no abnormal signs were observed during the study.Individual results of dermal scoring for the challenge appear in Table 2.

11.0 Conclusion

The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor’s responsibility.

12.0 Compliance

US FDA Good Laboratory Practice Regulations 21 CFR 58, effective June 20, 1979, as amended 52 FR 33780,

Sept. 4, 1987, and subsequent amendments

Standard operating procedure of CCIC Huatongwei International Inspection (Suzhou) Co., Ltd.

13.0 Record

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

14.0 Confidentiality agreement

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

15.0 Protocol amendment/deviations

There were no amendments or deviations that occurred during the course of this study.

Table 2 Guinea pig Sensitization Dermal Reactions

Group		No.	Pretest weight(g)	Finished weight(g)	The Challenge patch was removed 24h later		The Challenge patch was removed 48h later		Positive rate
					Erythema	Swelling	Erythema	Swelling	
SC	Test article	1	312.8	377.7	0	0	0	0	0%
		2	304.2	368.2	0	0	0	0	
		3	313.9	378.7	0	0	0	0	
		4	308.0	372.7	0	0	0	0	
		5	304.4	368.3	0	0	0	0	
		6	315.0	379.2	0	0	0	0	
		7	307.1	371.1	0	0	0	0	
		8	316.7	380.6	0	0	0	0	
		9	305.1	370.1	0	0	0	0	
		10	317.6	381.4	0	0	0	0	
	Negative Control	11	307.1	371.1	0	0	0	0	0%
		12	311.1	374.9	0	0	0	0	
		13	309.1	373.9	0	0	0	0	
		14	310.2	374.7	0	0	0	0	
		15	313.3	378.3	0	0	0	0	
SO	Test article	16	317.2	382.3	0	0	0	0	0%
		17	309.0	372.9	0	0	0	0	
		18	313.9	378.9	0	0	0	0	
		19	315.2	379.4	0	0	0	0	
		20	309.1	373.2	0	0	0	0	
		21	311.9	378.4	0	0	0	0	
		22	303.7	368.9	0	0	0	0	
		23	313.3	378.5	0	0	0	0	
		24	307.2	372.6	0	0	0	0	
		25	303.5	370.0	0	0	0	0	
	Negative Control	26	314.5	379.6	0	0	0	0	0%
		27	306.5	372.0	0	0	0	0	
		28	316.0	381.3	0	0	0	0	
		29	304.2	369.9	0	0	0	0	
		30	316.9	383.2	0	0	0	0	

Table 3 Positive control

Group	No.	Pretest weigh(g)	Finished weigh(g)	The Challenge patch was removed 24 h later		The Challenge patch was removed 48 h later		Positive rate
				Erythema	Swelling	Erythema	Swelling	
Positive Article Group	1	314.1	375.1	2	2	2	2	100%
	2	304.2	361.5	1	0	1	0	
	3	312.6	379.8	1	1	1	1	
	4	308.7	368.7	1	2	1	2	
	5	311.5	378.4	1	0	1	1	
	6	308.4	368.7	2	0	2	1	
	7	313.7	378.4	2	1	3	2	
	8	309.2	367.8	1	1	2	1	
	9	317.3	386.7	1	0	1	1	
	10	315.1	376.2	1	1	2	1	
Solution Control Group	11	307.2	365.4	0	0	0	0	0%
	12	313.5	379.1	0	0	0	0	
	13	304.9	367.6	0	0	0	0	
	14	315.1	377.5	0	0	0	0	
	15	308.7	363.4	0	0	0	0	

Note：The positive control was CSTBB21120001P1 (Finish date：2021-12-24)

中国认可
国际互认
检测
TESTING
CNAS L13034

Skin Irritation Test

Extraction Method

Final Report

Verification

Report Number: CSTBB2022020080

Article Name: 3DMASK EXTREMEPRO

Method Standard: ISO 10993-10: 2010

Sponsor

Savewo Limited

Hong Kong, China

Test Facility

CCIC Huatongwei International Inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

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Notices

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 report is only responsible for the test results of the tested samples.
5. The report shall not be reproduced except in full without the written approval of the company.
6. ISO 10993-2:2006 and ISO 10993-12:2021 are not within the scope of qualification.

Abstract

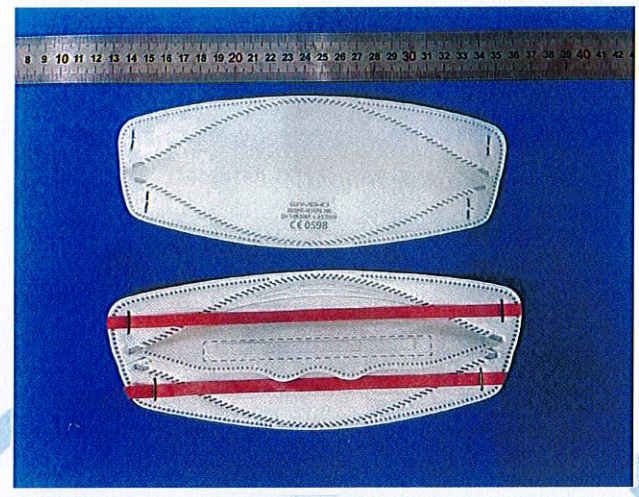
In this study, we took New Zealand white Rabbits to observe the skin irritation of the test article according to ISO 10993-10:2010.

The test article were extracted by 0.9 % Sodium Chloride Injection and Sesame Oil. Apply 0.5 ml extracts of test article or control to 2.5 cm×2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit, and then wrap the application sites with a bandage for a minimum of 4 h. At the end of the contact time, remove the dressing. The describe and score the skin reaction for erythema and oedema 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.

The results showed that the rabbits in the negative control group (0.9 % Sodium Chloride Injection, Sesame Oil) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (SDS). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article has no skin irritation on rabbits.

Study Verification and Signature



Protocol Number	SST2201001406BB
Protocol Effective Date	2022-01-07
Technical Initiation Date	2022-01-07
Technical Completion Date	2022-01-14
Final Report Completion Date	2022-02-18

Personnel — Betty Zhuang — 2022-02-18 (Date Completed)

Approved — Hongxia Li (Study Director) — 2022-02-18 (Date Completed)

Supervisory — (Test Facility Manager) — 2022-02-18 (Date Completed)

CCIC Huatongwei International Inspection (Suzhou) Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the HTW's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase Inspected	Date	Study Director	Management
Experiment	2022-01-07	2022-01-07	2022-01-07
Raw Data	2022-01-14	2022-01-14	2022-01-14
Final Report	2022-02-18	2022-02-18	2022-02-18

The findings of these inspections have been reported to Management and the Study Director.

Quality Assurance

2022-02-18
Date

GLP Statement

This study was conducted in compliance with current U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of HTW, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Hongxia Li
Study Director

2022-02-18
Date

1.0 Purpose

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

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 2: Animal welfare requirements (ISO 10993-2:2006)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2021)

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	3DMASK EXTREMEPRO	0.9% Sodium Chloride Injection(SC)	Sesame Oil (SO)	Sodium dodecyl sulfate (SDS)
Manufacturer	Savewo Limited	Guangxi Yuyuan Pharmaceutical Co., Ltd	Zhejiang Tianyu yam Oil Co., Ltd	Solarbio
Size	220mm X 85mm	500 ml	1L	500 g
Model	Not Provided	/	/	/
Lot Batch#	Not Provided	H21011707	MX20210401	1019Y032
Test Article Material	polypropylene non-woven fabric, polypropylene terephthalate fabric, polypropylene melt-blown fabric, Polyisoprene Straps, Stainless Steel staples, Polychloroethylene Nose and Chin foam, Aluminium Nose Clip	/	/	/
Physical State	Not Provided	Liquid	Liquid	Solid
Color	(Red Straps)	Colorless	Light yellow	White
Package	PE and paper	/	/	/

material				
Sterilized or Not	Not Sterilized	/	/	/
Concentration	/	0.9 %	/	working concentration 10 %
Surface (cm^2)	Not Provided	/	/	/
Weight (g)	Not Provided	/	/	/
Storage Condition	Room Temp.	Room Temp.	Room Temp.	Room Temp.
The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification of test system

4.1 Test animal

Species: New Zealand white Rabbit

Number: 6

Sex: either sex

Weight: >2 kg

Health status: Healthy, not previously used in other experimental procedures. Female animals were nul liparous and not pregnant.

Animal identification: Ear tattoo

Cages: Stainless steel cage

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

4.2 Justification of test system

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the c urrent testing standards. Positive control 10% sodium dodecyl sulfate has been substantiated at HTW with this method.

5.0 Animal management

Animal purchase: Wuxi hengtai experimental animal breeding co. LTD SCXK (SU) 2020-0003

Feed: Experimental rabbits were fed a maintenance diet, Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

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

Animal room temperature: 18-26 ℃

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, or bedding expected to interfere with the test data

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2021/03/11), Electronic scale (SHB020, calibration data: 2021/03/11)

7.0 Experiment design

7.1 Sample preparation

The extracts of test article will be prepared according to the following steps:

Aseptic Sampling		Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Reagent		Condition	pH
Whole	731.0 cm^2	6 cm^2: 1 ml	SC	121.8 ml	50 ℃ / 72 h/ 60rpm	5.5
	731.0 cm^2		SO	121.8 ml		/

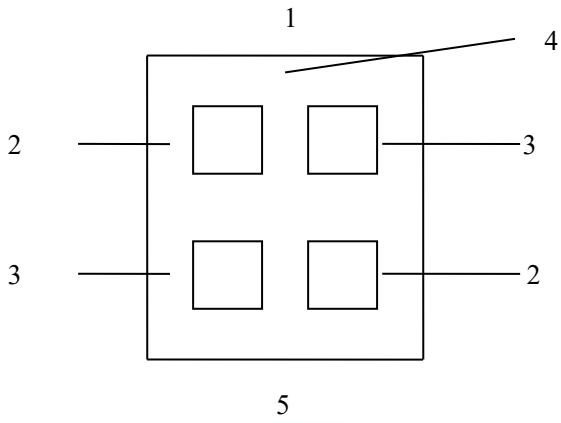
Both induction and challenge phase extracts were prepared by the number of times. The state of the leaching solution did not change visually after the leaching was advanced.The control solution was prepared under the same conditions.The extraction of the test article could be stored at room temperature for no more than 24 h. No particulates or color changes were observed in pre- and post-extraction, the color and pH of the extraction solution did not change before and after use,and the pH value was 5.5, the status of the extract was shown in the table below.

Vehicle	Time Observed	Extracts	Condition of Final Extracts		
			Color	Clear or Not	Particulates
0.9% Sodium Chloride Injection(SC)	Before Extraction	Test article	Colorless	Clear	None
		Negative Control	Colorless	Clear	None
	After Extraction	Test article	Colorless	Clear	None
		Negative Control	Colorless	Clear	None
Sesame Oil (SO)	Before Extraction	Test article	Light yellow	Clear	None
		Negative Control	Light yellow	Clear	None
	After Extraction	Test article	Light yellow	Clear	None
		Negative Control	Light yellow	Clear	None

7.2 Test method

Use the rabbits with healthy intact skin. Fur was generally clipped within 24 h period 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 0.5 ml extract (s) of test article or control to 2.5 cm×2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit as shown in Figure 1, 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.



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

Figure1 Location of skin application sites

8.0 The results observed

The 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
Maximal 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

9.0 Evaluation criteria

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 were totalled separately for each test article and blank for each animal. 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).

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

When blank or negative control was 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.

10.0 Results of the test

All animals were survived and no abnormal signs were observed during the study. According to what observed, the response of skin on testing side did not exceed that on the control side. Thus, the primary irritation index for the test article was calculated to be 0. See table 2.

11.0 Conclusion

Based on the above results, it can be concluded that under the experimental conditions, the test article has no skin irritation on rabbits. Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor’s responsibility.

12.0 Compliance

US FDA Good Laboratory Practice Regulations 21 CFR 58, effective June 20, 1979, as amended 52 FR 33780, Sept. 4, 1987, and subsequent amendments

Standard operating procedure of CCIC Huatongwei International Inspection (Suzhou) Co., Ltd.

13.0 Record

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14.0 Confidentiality agreement

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

15.0 Protocol amendment/deviations

There were no amendments or deviations that occurred during the course of this study.

Table 2 Skin irritation response observation

Reagent	Rabbit No.	Pretest weight(kg)	Finished weight(kg)	Group	Reaction	Interval (hours): score=left/right			
						1±0.1h	24±2 h	48±2 h	72±2 h
SC	1	2.23	2.34	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	2	2.15	2.26	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	3	2.20	2.31	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
Primary irritation index						0			
SO	4	2.18	2.29	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	5	2.25	2.36	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	6	2.16	2.27	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
Primary irritation index						0			

Table 3 Positive control

Rabbit No.	Group	Reaction	Interval (hours): score=left site/right site			
			1±0.1 h	24±2 h	48±2 h	72±2 h
1	Positive Article Group	Erythema	1/1	2/3	2/3	3/4
		Oedema	0/1	2/2	3/3	4/4
	Solution Control Group	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
2	Positive Article Group	Erythema	0/1	1/2	2/3	3/3
		Oedema	0/0	2/2	3/3	4/3
	Solution Control Group	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
3	Positive Article Group	Erythema	0/1	1/2	3/3	4/4
		Oedema	0/0	2/1	3/4	3/4
	Solution Control Group	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
Primary irritation index			5.6			

Positive control performed once every six months see CSTBB21120002P1(Finish date：2021-12-10)

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检测
TESTING
CNAS L13034

Skin Sensitization Test

Guinea Pig Maximization

Final Report

Verification

Report Number: CSTBB2022020079

Article Name: 3DMASK EXTREMEPRO

Method Standard: ISO 10993-10: 2010

Sponsor

Savewo Limited

Hong Kong, China

Test Facility

CCIC Huatongwei International Inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

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6. ISO 10993-2:2006 and ISO 10993-12:2021 are not within the scope of qualification.

Abstract

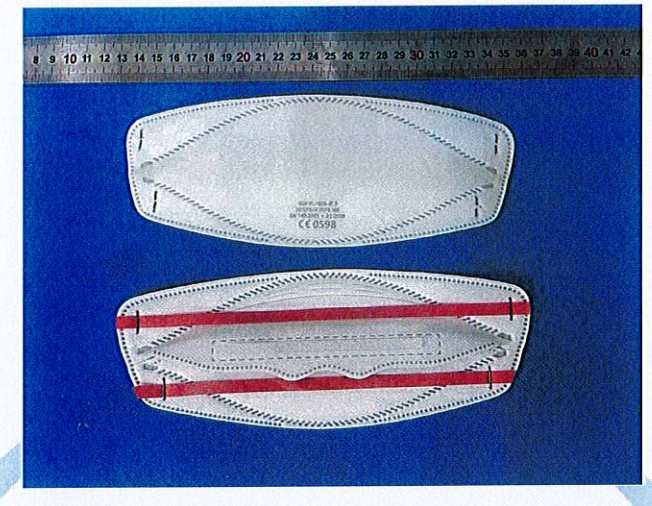
In this study, we took guinea pigs to observe the skin sensitization of the test article according to ISO 10993-10: 2010.

The test article were extracted by 0.9% Sodium Chloride Injection and Sesame Oil. The extract was mixed with Fresch's complete adjuvant into a stable emulsifier. Intradermal induction and topical induction were operated in the clipped intrascapular region of each animal. At 14d after completion of the topical induction phase, Challenge all test and control animals with the test sample at sites that were not treated during topical induction phase. The erythema and edema of the challenge site were observed to test the sensitization response of the test article. According to the Magnusson and Kligman scales, the response to erythema and edema at each application site of the skin was described and scored 24 hours and 48 hours after the challenge phase.

The results showed that the guinea pigs in the negative control group (0.9% Sodium Chloride Injection, Sesame Oil) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (DNCB). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article has no potential skin sensitization on guinea pigs in the extraction method.

Study Verification and Signature



Protocol Number	SST2201001405BB
Protocol Effective Date	2022-01-07
Technical Initiation Date	2022-01-07
Technical Completion Date	2022-02-04
Final Report Completion Date	2022-02-18

Personnel Berry Zhang 2022-02-18
Date Completed

Approved Hongtia Li
Study Director
2022-02-18
Date Completed

Supervisory
Test Facility Manager
2022-02-18
Date Completed

CCIC Huatongwei International Inspection (Suzhou) Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the HTW's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase Inspected	Date	Study Director	Management
Experiment	2022-01-07	2022-01-07	2022-01-07
Raw Data	2022-02-04	2022-02-04	2022-02-04
Final Report	2022-02-18	2022-02-18	2022-02-18

The findings of these inspections have been reported to Management and the Study Director.

Quality Assurance

2022-02-18
Date

GLP Statement

This study was conducted in compliance with current U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of HTW, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Hongtia Li
Study Director

2022-02-18
Date

1.0 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

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 2: Animal welfare requirements (ISO 10993-2:2006)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2021)

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	3DMASK EXTREMEPRO	0.9% Sodium Chloride Injection(SC)	Sesame Oil (SO)	2, 4-Dinitrochlorobenzene (DNCB)
Manufacturer	Savewo Limited	Guangxi Yuyuan Pharmaceutical Co., Ltd	Zhejiang Tianyu yam Oil Co., Ltd	TOKYO CHEMICAL INDUSTRY CO., LTD
Size	220mm X 85mm	500 ml	1L	25 g
Model	Not Provided	/	/	/
Lot Batch#	Not Provided	H21011707	MX20210401	H2UKD-DM
Test Article Material	polypropylene non-woven fabric, polypropylene terephthalate fabric, polypropylene melt-blown fabric, Polyisoprene Straps, Stainless Steel staples, Polychloroethylene Nose and Chin foam, Aluminium Nose Clip	/	/	/
Physical State	Not Provided	Liquid	Liquid	Solid

Color	(Red Straps)	Colorless	Light yellow	Light yellow
Package material	PE and paper	/	/	/
Sterilized or Not	Not Sterilized	/	/	/
Concentration	/	0.9 %	/	Induction Concentration: 0.1 % Challenge Concentration: 0.05 % Dissolved in ethanol
Surface (cm^2)	Not Provided	/	/	/
Weight (g)	Not Provided	/	/	/
Storage Condition	Room Temp.	Room Temp.	Room Temp.	Room Temp.
The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification of test system

4.1 Test animal

Species: Hartley Guinea Pig (Cavia Porcellus)

Number: 30 (20 Test +10 Control)

Sex: either sex

Initial body weight: 300.0~500.0 g

Health status: Healthy, not previously used in other experimental procedures. Female animals were nul liparous and not pregnant.

Animal identification: Ear tag

Cages: Plastic cage

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

4.2 Justification of test system

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1 970). The guinea pig is believed to be the most sensitive animal model for this type of study. DNCB is the positive control article recommended in the test instructions. To ensure the sensitivity of the experime ntal system, the positive control article should be verified every three months.

5.0 Animal management

Animal purchase: Wuxi hengtai experimental animal breeding co. LTD SCXK (SU) 2020-0003

Bedding: Corncob Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Feed: Guinea pigs were fed with full-price pellets Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

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

Animal room temperature: 18-26 ℃

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, or bedding expected to interfere with the test data.

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2021/03/11), Electronic scale (SHB017, calibration data: 2021/03/11)

6.2 Reagents

Freund’s adjuvant Complete liquid (SIGMA, Lot No: SLCC3348), Sodium dodecyl sulfate (Solarbio, Lot No: 1019Y032)

7.0 Experiment design

7.1 Sample preparation

The extracts of test article will be prepared according to the following steps:

Aseptic Sampling			Extraction in sterile vessels				
	Sampling Manner	Actually sampling	Ratio	Reagent		Condition	pH
Intradermal induction phase I	Whole	731.0 cm^2	6 cm^2: 1 ml	SC	121.8 ml	50 ℃ / 72 h/ 60rpm	5.5
		731.0 cm^2		SO	121.8 ml		/
Topical induction phaseII	Whole	731.0 cm^2	6 cm^2: 1 ml	SC	121.8 ml	50 ℃ / 72 h/ 60rpm	5.5
		731.0 cm^2		SO	121.8 ml		/
Challenge phase	Whole	731.0 cm^2	6 cm^2: 1 ml	SC	121.8 ml	50 ℃ / 72 h/ 60rpm	5.5
		731.0 cm^2		SO	121.8 ml		/

Both induction and challenge phase extracts were prepared by the number of times. The state of the leaching solution did not change visually after the leaching was advanced. The control solution was prepared under the same conditions.The extraction of the test article could be stored at room temperature. for no more than 24 h. No particulates or color changes were observed in pre- and post-extraction, the color and pH of the extraction solution did not change before and after use,and the pH value was 5.5, the status of the extract was shown in the table below.

Phase	Vehicle	Time Observed	Extracts	Condition of Final Extracts		
				Color	Clear or Not	Particulates
Intradermal induction phase I	0.9% Sodium Chloride Injection(SC)	Before Extraction	Test article	Colorless	Clear	None
			Negative Control	Colorless	Clear	None
		After Extraction	Test article	Colorless	Clear	None
			Negative Control	Colorless	Clear	None

	Sesame Oil (SO)	Before Extraction	Test article	Light yellow	Clear	None
			Negative Control	Light yellow	Clear	None
		After Extraction	Test article	Light yellow	Clear	None
			Negative Control	Light yellow	Clear	None
Topical induction phaseII	0.9% Sodium Chloride Injection(SC)	Before Extraction	Test article	Colorless	Clear	None
			Negative Control	Colorless	Clear	None
		After Extraction	Test article	Colorless	Clear	None
			Negative Control	Colorless	Clear	None
	Sesame Oil (SO)	Before Extraction	Test article	Light yellow	Clear	None
			Negative Control	Light yellow	Clear	None
		After Extraction	Test article	Light yellow	Clear	None
			Negative Control	Light yellow	Clear	None
Challenge phase	0.9% Sodium Chloride Injection(SC)	Before Extraction	Test article	Colorless	Clear	None
			Negative Control	Colorless	Clear	None
		After Extraction	Test article	Colorless	Clear	None
			Negative Control	Colorless	Clear	None
	Sesame Oil (SO)	Before Extraction	Test article	Light yellow	Clear	None
			Negative Control	Light yellow	Clear	None
		After Extraction	Test article	Light yellow	Clear	None
			Negative Control	Light yellow	Clear	None

7.2 Test method

7.2.1 Intradermal induction phaseI

Make a pair of 0.1 ml intradermal injections of each of the following, into each animal, at the injection sites (A, B and C) , as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 volume ratio stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.

Site B: The test sample (undiluted extract); inject the control animals with the extraction solvent alone.

Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent; inject the control animals with an emulsion of the blank liquid with adjuvant.

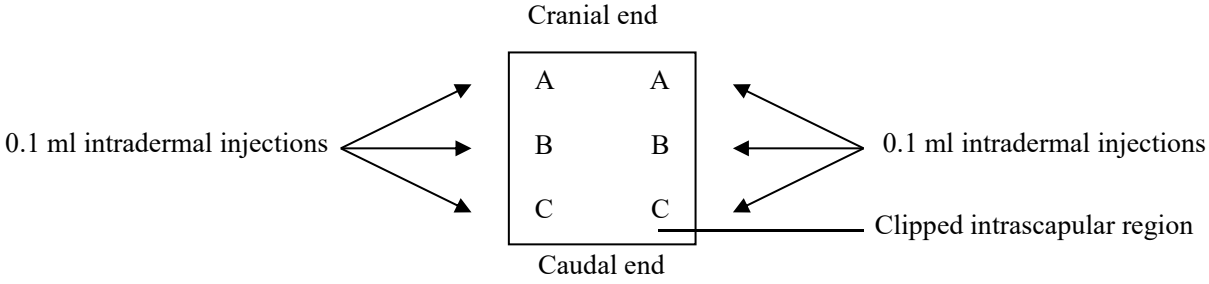


Figure 1 Location of intradermal injection sites

7.2.2 Topical induction phaseII

At (7±1) d after the intradermal induction phase, administer the test article extract by topical application to the intrascapular region of each animal, using a patch of area approximately 8cm^2 (absorbent gauze), so as to cover the intradermal injection sites. If the maximum concentration that can be achieved in Intradermal induction phase I does not produce irritation, pretreat the area with 10% sodium dodecyl sulfate(SDS) massaged into the skin (24±2) h before the patch is applied. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48±2) h.

Treat the control animals similarly, using the blank liquid alone.

7.2.3 Challenge phase

All test and control animals shall be challenged at 14 d after completion of the topical induction phase. Absorbent gauzes (2.5 cm x 2.5 cm) were soaked respectively with test article and control article. Apply the test article extract and control article topically to two sites that were not treated during the induction stage. The patches shall be secured with an occlusive dressing. Dressings and patches shall be removed after (24±2) h.

8.0 The results observed

Observe the appearance of the challenge skin sites of the test and control animals (24±2) h and (48±2) h after removal of the dressings. Use of natural lighting is highly recommended in order to visualize the skin reactions. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading scale 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. The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

10.0 Results of the test

All animals were survived and no abnormal signs were observed during the study.Individual results of dermal scoring for the challenge appear in Table 2.

11.0 Conclusion

The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor’s

responsibility.

12.0 Compliance

US FDA Good Laboratory Practice Regulations 21 CFR 58, effective June 20, 1979, as amended 52 FR 33780, Sept. 4, 1987, and subsequent amendments

Standard operating procedure of CCIC Huatongwei International Inspection (Suzhou) Co., Ltd.

13.0 Record

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

14.0 Confidentiality agreement

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

15.0 Protocol amendment/deviations

There were no amendments or deviations that occurred during the course of this study.

Table 2 Guinea pig Sensitization Dermal Reactions

Group		No.	Pretest weight(g)	Finished weight(g)	The Challenge patch was removed 24h later		The Challenge patch was removed 48h later		Positive rate
					Erythema	Swelling	Erythema	Swelling	
SC	Test article	1	314.5	379.7	0	0	0	0	0%
		2	304.4	369.5	0	0	0	0	
		3	313.9	378.8	0	0	0	0	
		4	308.0	372.9	0	0	0	0	
		5	304.3	368.2	0	0	0	0	
		6	315.1	379.3	0	0	0	0	
		7	306.9	371.1	0	0	0	0	
		8	316.8	381.0	0	0	0	0	
		9	305.0	368.9	0	0	0	0	
		10	317.6	381.8	0	0	0	0	
	Negative Control	11	306.4	371.9	0	0	0	0	0%
		12	310.7	374.8	0	0	0	0	
		13	308.5	374.0	0	0	0	0	
		14	309.8	374.7	0	0	0	0	
		15	313.5	378.0	0	0	0	0	
SO	Test article	16	317.5	382.3	0	0	0	0	0%
		17	309.6	373.5	0	0	0	0	
		18	313.9	377.9	0	0	0	0	
		19	315.7	379.7	0	0	0	0	
		20	308.8	373.1	0	0	0	0	
		21	313.8	378.9	0	0	0	0	
		22	303.8	369.8	0	0	0	0	
		23	313.4	378.8	0	0	0	0	
		24	307.1	372.5	0	0	0	0	
		25	303.6	368.9	0	0	0	0	
	Negative Control	26	314.4	380.6	0	0	0	0	0%
		27	306.5	372.7	0	0	0	0	
		28	316.3	381.4	0	0	0	0	
		29	304.1	369.5	0	0	0	0	
		30	317.0	382.0	0	0	0	0	

Table 3 Positive control

Group	No.	Pretest weigh(g)	Finished weigh(g)	The Challenge patch was removed 24 h later		The Challenge patch was removed 48 h later		Positive rate
				Erythema	Swelling	Erythema	Swelling	
Positive Article Group	1	314.1	375.1	2	2	2	2	100%
	2	304.2	361.5	1	0	1	0	
	3	312.6	379.8	1	1	1	1	
	4	308.7	368.7	1	2	1	2	
	5	311.5	378.4	1	0	1	1	
	6	308.4	368.7	2	0	2	1	
	7	313.7	378.4	2	1	3	2	
	8	309.2	367.8	1	1	2	1	
	9	317.3	386.7	1	0	1	1	
	10	315.1	376.2	1	1	2	1	
Solution Control Group	11	307.2	365.4	0	0	0	0	0%
	12	313.5	379.1	0	0	0	0	
	13	304.9	367.6	0	0	0	0	
	14	315.1	377.5	0	0	0	0	
	15	308.7	363.4	0	0	0	0	

Note：The positive control was CSTBB21120001P1 (Finish date：2021-12-24)

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检测
TESTING
CNAS L2954

Final Report

Report Number: SDWH-M202106929-2(E)

Skin Sensitization Test of Savewo ClassicMask

According to ISO 10993-10:2010
Guinea Pig Maximization Test
0.9% Sodium Chloride Injection Extract

Sponsor: Savewo Limited

Address: 1/F, 266-270 Texaco Road, Tsuen Wan, Hong Kong

Sanitation & Environment Technology Institute, Soochow University
Address: 199 Ren-Ai Road, Suzhou Industrial Park, Suzhou, Jiangsu 215123, P. R. China
Website: www.sudatest.com
E-mail: med@sudatest.com
Direct: +86 512 65880038
Free: 400 107 8828

Content

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 inspection and 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 results relate only to the articles tested.

(5) The report shall not be reproduced except in full without the written approval of the institute.

Quality Assurance Statement

The Quality Assurance Unit inspected/audited this study in compliance with the following GLP regulations:
Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA).

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the Testing Facility Management. The final report was reviewed by the Quality Assurance Unit. The final report accurately describes the test methods in accordance with standard operating procedures, and the results are consistent with raw data of non-clinical studies conducted according to the study protocol.

Inspections	Date of Inspection	Date Reported to Study Director	Date Reported to Testing Facility Management.
Study Protocol	2021-12-17	2021-12-17	2022-01-18
Study Procedure	2022-01-07 2022-01-11	2022-01-07 2022-01-11	2022-01-18
Raw Data	2022-01-18	2022-01-18	2022-01-18
Final Report	2022-01-18	2022-01-18	2022-01-18

Quality Assurance Unit: Xu Qian — 2022-01-18

Quality Assurance — Date

GLP Compliance Statement

This study was fully in accordance with the technical requirements of the study protocol.

This study was conducted in compliance with Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA).

Verification Dates

Test Article Receipt	2021-12-15
Protocol Effective Date	2021-12-17
Technical Initiation Date	2021-12-17
Technical Completion Date	2022-01-14
Final Report Completion Date	2022-01-19

Edited by: Xu Yixuan 2022-01-17
Date

Reviewed by: Zhang Yan 2022-01-19
Study Director Date

Approved by: Fangjingxi 2022-01-19
Authorized Signatory Date

Sanitation & Environment Technology Institute, Soochow University

Summary

1 Test Article

Test Article Name	Savewo ClassicMask
Manufacturer	Savewo Limited
Address	1/F, 266-270 Texaco Road, Tsuen Wan, Hong Kong
Model	ClassicMask
Lot/Batch	Lot 21212280

2 Main Reference

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

3 Test Method

Potential skin sensitization of test article was evaluated using guinea pig maximization test in accordance with ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.
Study protocol number: SDWH-PROTOCOL-GLP-M202106929-2.

4 Conclusion

Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig. The positive rate of sensitization was 0%. No evidence of skin sensitization in guinea pigs was found.

Test Report

1 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

2 Reference

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

3 Compliance

Good Laboratory Practice Regulations, 21 CFR, Part 58.
ISO/IEC 17025:2017 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 Registration No. CNAS L2954.
RB/T 214—2017 Competence assessment for inspection body and laboratory mandatory approval—General requirements for inspection body and laboratory Certification and Accreditation Administration of the People's Republic of China INSPECTION BODY AND LABORATORY MANDATORY APPROVAL Certificate No. CMA 180015144061.

4 Identification of Test and Control Articles

4.1 Test Article

Test Article Name	Savewo ClassicMask
Manufacturer	Savewo Limited
Address	1/F, 266-270 Texaco Road, Tsuen Wan, Hong Kong
Test Article Initial State	Non-sterile
CAS Number	Not supplied by sponsor (N/S)
Model	ClassicMask
Size	175 x 95mm
Lot/Batch	Lot 21212280
Raw Material	N/S
Packaging Material	N/S
Physical State	Solid
Color	White
Density	N/S
Stability	N/S
Solubility	N/S
Storage Condition	Room temperature
Intended Use	Surgical Mask is intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganism, blood, body fluids, and particulate materials.Surgical Mask is intended for use in infection control practices to reduce potential exposure to blood and body fluids.
Additional Information	Lot 21212280

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

The Sponsor is responsible for all test article characterization data as specified in the GLP regulations.

4.2 Control Article

4.2.1 Negative Control

Name: 0.9% Sodium Chloride Injection (SC)
Manufacturer: Guangxi Yuyuan Pharmaceutical Co., Ltd.
Size: 500mL
Lot/ Batch#: H21062603
Physical State: Liquid
Color: Colorless
Storage Condition: Room Temperature

4.2.2 Positive Control

Name: 2, 4-Dinitrochlorobenzene (DNCB)
Manufacturer: Chengdu Aikeda Chemical Reagent Co., Ltd.
Size: 100g
Lot/ Batch#: 201904101
Induction Concentration: 0.5%
Challenge Concentration: 0.1%
Solvent: 0.9% Sodium Chloride Injection
Date prepared: Intradermal Induction Phase I :2021-11-15; Topical Induction Phase II: 2021-11-22;
Challenge Phase: 2021-12-07
Physical State: Liquid
Color: Light Yellow
Storage Condition: Room Temperature

5 Equipment and Reagents

5.1 Equipment

Equipment Name	Equipment Number	Calibration Expire
Electronic scale	SDWH442	2022-04-06
Horizontal Large Capacity Constant Temperature Vibrator	SDWH2671	2022-11-25
Electronic Balance	SDWH2601	2022-05-11
Steel straight scale	SDWH463	2022-06-29
Vertical pressure steam sterilizer	SDWH2204	2022-03-09

5.2 Reagents

Reagent Name	Manufacturer	LOT
Freund's adjuvant, complete liquid	SIGMA	SLCG1631
Sodium dodecyl sulfate (SDS)	Sinopharm Chemical Reagent Co., Ltd	20210105

6 Identification of Test System

Species: Hartley guinea pig (Cavia Porcellus)
Number: 15 (10 test +5 negative control)
Sex: Male
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, test code and first treatment date, etc.
Animal identification: Stain with dyeing liquid
Cages: plastic cage
Acclimation period: 7 days under the same conditions as for the actual test

7 Animal Care and Maintenance

Animal source: Suzhou Experimental Animal Sci-Tech Co., Ltd. <Permit Code: SCXK (SU) 2020-0007>
Bedding: corncob, Suzhou Shuangshi Laboratory Animal Feed Science Co., Ltd.
Feed: guinea pig diet, Suzhou Experimental Animal Sci-Tech Co., Ltd.
Water: drinking water met the Standards for Drinking Water Quality GB 5749–2006
Animal room temperature: 18 ~ 26°C
Animal room relative humidity: 30% ~ 70%
Lights: 12 h 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, or bedding expected to interfere with the test data.

8 Justification of Test System and Route of Administration

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, 2,4-dinitrochlorobenzene (DNCB) has been substantiated at SDWH (listed in **Table 1** and **Table 2**).
The test article was extracted and administered in vivo through a medium compatible with the test system. Dermal application corresponds to the likely route of human exposure.

9 Experimental Design

9.1 Preparation of Extracts

9.1.1 Pretreatment

No pretreatment required.

9.1.2 Extraction

Under aseptic conditions, samples were taken according to the sampling method (Whole sampling, excluding the nose clip, add additional volume of extraction vehicle that the test sample absorbs when performing the extraction, using the data of the combined area of all tissue contacting surfaces of each sample provided by the sponsor as the standard surface area, 166.25 cm^2). The extraction was performed with agitation in closed inert containers according to the extraction ratio listed in the following table (sample: extraction vehicle). The extraction vehicle was 0.9% Sodium Chloride Injection (SC).

Test Period	Actual Sampling	Extract Procedure			Final Extract
		Extract Ratio	SC	Condition	
Intradermal Induction Phase I	Surface area 166.25 cm^2	3 cm^2 : 1 mL	64.9 mL	50°C, 72 h	Clear
Topical Induction Phase II	Surface area 166.25 cm^2	3 cm^2 : 1 mL	64.9 mL	50°C, 72 h	Clear
Challenge Phase	Surface area 166.25 cm^2	3 cm^2 : 1 mL	64.9 mL	50°C, 72 h	Clear

The state of the extract did not change after extraction. The extract was stored at room temperature, and tested within 24 h, without the process of adjusting its pH value, filtering, centrifuging, diluting, etc.
The vehicle (without the test article) was similarly prepared to serve as the control.

9.2 Experimental Procedure

9.2.1 Animal Preparation and Grouping

On the first day of treatment, 15 guinea pigs were weighed and identified. The fur from the dorsoscapular area of the animals was removed with an electric clipper. Grouping as follow:

Group Name	Group Size	Gender
Test	10 animals	Male
Negative Control	5 animals	Male

9.2.2 Intradermal Induction Phase I

A pair of 0.1 mL intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.
Site A: A 50:50 (*V*/*V*) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.
Site B: the test sample (undiluted extract); the control animals were injected with the solvent alone.
Site C: the test sample at the concentration used at site B, emulsified in a 50:50 (*V*/*V*) stable emulsion of Freund's complete adjuvant and the solvent (50%); inject the control animals with an emulsion of the blank liquid with adjuvant.

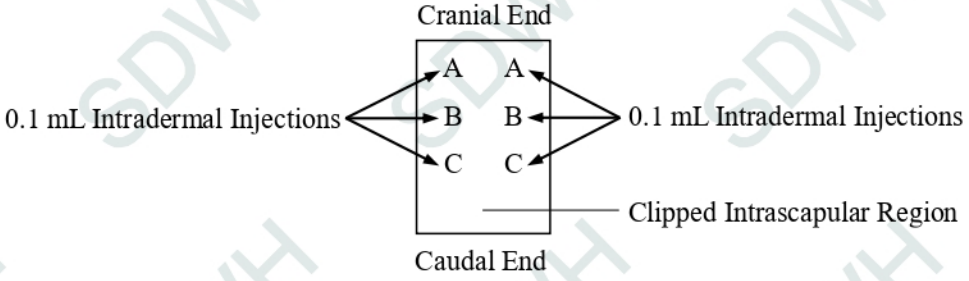

Figure 1 Locations of intradermal injection sites

9.2.3 Topical Induction Phase II

The maximum concentration that can be achieved in Intradermal induction phase I did not produce irritation. Animals are pretreated with 10% sodium dodecyl sulfate (Solvent: Distilled water, Date prepared: 2021-11-15) (24 ± 2) h before the topical induction application.
At 7 ± 1 d after completion of the intradermal induction phase, administer 0.5 mL test article extract by topical application to the intrascapular region of each animal, using a patch of area approximately 8 cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48 ± 2) h.
Treat the control animals similarly, using the blank liquid alone.

9.2.4 Challenge Phase

At 14 ± 1 d after completion of the topical induction phase, challenge all test and control animals with the test sample. Administer 0.5 ml test article extract and control article by topical application to sites that were not treated during the induction stage, using absorbent gauze (8 cm^2) soaked in the test article extract or control article. Secure with an occlusive dressing. Remove the dressings and patches after (24 ± 2) h.

9.3 Observation of Animals

Observe the appearance of the challenge skin sites of the test and control animals (24 ± 2) h and (48 ± 2) h after removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in the following table for each challenge site and at each time interval.

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

9.4 Evaluation of Results

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.

The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

10 Results

The results of skin reaction after challenge were listed in **Table 3**. No skin sensitization reaction was found in the skin of guinea pigs using extracts of the test article, and the positive rate of sensitization was 0%.

The positive rate of sensitization in the positive control group was 100%, listed in **Table 1**.

Clinical observations and weight changes of guinea pigs were listed in **Table 4.**

11 Conclusion

Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig.

12 Record Storage

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

13 Confidentiality Agreement

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

14 Deviation Statement

There were no deviations from the approved study protocol which were judged to have any impact on the validity of the data.

Annex 1 Test Data

Table 1 Guinea pig sensitization dermal reactions of positive control

Group	Animal Number	(24 ± 2) h Before Phase II Patch Application		(24 ± 2) h Following Challenge Phase		(48 ± 2) h Following Challenge Phase		Positive Rate after Challenge Phase
		Left	Right	Test Sites	Control Sites	Test Sites	Control Sites	
Positive Control	1	3	3	2	0	1	0	100%
	2	3	3	2	0	2	0	
	3	3	2	2	0	1	0	
	4	2	3	3	0	2	0	
	5	3	3	2	0	2	0	
Negative Control	6	0	0	0	0	0	0	-
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	

Note: the data of positive control come from SDWH- M202106058-1 (Completed Date: 2021-12-10)

Table 2 Weigh change and clinical observation of positive control

Group	Animal Number	Weight (g)		Clinical Observation Except Dermal Reactions
		Before Injection	After Experiment	
Positive Control	1	312	375	Normal
	2	314	380	Normal
	3	306	372	Normal
	4	321	388	Normal
	5	333	412	Normal
Negative Control	6	346	434	Normal
	7	334	411	Normal
	8	321	392	Normal
	9	312	376	Normal
	10	341	423	Normal

Note: the data of positive control come from SDWH- M202106058-1 (Completed Date: 2021-12-10)

Table 3 Guinea pig sensitization dermal reactions

Group	Animal Number	(24 ± 2) h Before Phase II Patch Application		(24 ± 2) h Following Challenge Phase		(48 ± 2) h Following Challenge Phase		Positive Rate after Challenge Phase
		Left	Right	Test Sites	Control Sites	Test Sites	Control Sites	
Test	1	0	0	0	0	0	0	0%
	2	0	0	0	0	0	0	
	3	0	0	0	0	0	0	
	4	0	0	0	0	0	0	
	5	0	0	0	0	0	0	
	6	0	0	0	0	0	0	
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	
Negative Control	11	0	0	0	0	0	0	-
	12	0	0	0	0	0	0	
	13	0	0	0	0	0	0	
	14	0	0	0	0	0	0	
	15	0	0	0	0	0	0	

Table 4 Weigh change and clinical observation

Group	Animal Number	Weight (g)		Clinical Observation Except Dermal Reactions
		Before Injection	After Experiment	
Test	1	332	412	Normal
	2	326	396	Normal
	3	345	430	Normal
	4	315	383	Normal
	5	355	445	Normal
	6	316	388	Normal
	7	331	407	Normal
	8	330	403	Normal
	9	319	387	Normal
	10	336	419	Normal
Negative Control	11	311	378	Normal
	12	321	388	Normal
	13	329	409	Normal
	14	333	414	Normal
	15	318	385	Normal

Annex 2 Photograph of Test Article

Annex 3 Information Provided by Sponsor

1 Production Process

Not supplied by sponsor.

2 Other Information

Not supplied by sponsor.

End of Report

180015144061

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检测
TESTING
CNAS L2954

Final Report

Report Number: SDWH-M202106929-3(E)

Skin Sensitization Test of Savewo ClassicMask

According to ISO 10993-10:2010
Guinea Pig Maximization Test
Sesame Oil Extract

Sponsor: Savewo Limited

Address: 1/F, 266-270 Texaco Road, Tsuen Wan, Hong Kong

Sanitation & Environment Technology Institute, Soochow University
Address: 199 Ren-Ai Road, Suzhou Industrial Park, Suzhou, Jiangsu 215123, P. R. China
Website: www.sudatest.com E-mail: med@sudatest.com
Direct: +86 512 65880038 Free: 400 107 8828

Content

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 inspection and 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 results relate only to the articles tested.

(5) The report shall not be reproduced except in full without the written approval of the institute.

Quality Assurance Statement

The Quality Assurance Unit inspected/audited this study in compliance with the following GLP regulations:
Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA).

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the Testing Facility Management. The final report was reviewed by the Quality Assurance Unit. The final report accurately describes the test methods in accordance with standard operating procedures, and the results are consistent with raw data of non-clinical studies conducted according to the study protocol.

Inspections	Date of Inspection	Date Reported to Study Director	Date Reported to Testing Facility Management.
Study Protocol	2021-12-17	2021-12-17	2022-01-18
Study Procedure	2022-01-07 2022-01-11	2022-01-07 2022-01-11	2022-01-18
Raw Data	2022-01-18	2022-01-18	2022-01-18
Final Report	2022-01-18	2022-01-18	2022-01-18

Quality Assurance Unit: Xu Qian — 2022-01-18

Quality Assurance — Date

GLP Compliance Statement

This study was fully in accordance with the technical requirements of the study protocol.

This study was conducted in compliance with Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA).

Verification Dates

Test Article Receipt	2021-12-15
Protocol Effective Date	2021-12-17
Technical Initiation Date	2021-12-17
Technical Completion Date	2022-01-14
Final Report Completion Date	2022-01-19

Edited by: Xu Yixuan 2022-01-17
Date

Reviewed by: Zhang Yan 2022-01-19
Study Director Date

Approved by: Fangjingxi 2022-01-19
Authorized Signatory Date

Sanitation & Environment Technology Institute, Soochow University

Summary

1 Test Article

Test Article Name	Savewo ClassicMask
Manufacturer	Savewo Limited
Address	1/F, 266-270 Texaco Road, Tsuen Wan, Hong Kong
Model	ClassicMask
Lot/Batch	Lot 21212280

2 Main Reference

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

3 Test Method

Potential skin sensitization of test article was evaluated using guinea pig maximization test in accordance with ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.
Study protocol number: SDWH-PROTOCOL-GLP-M202106929-3.

4 Conclusion

Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig. The positive rate of sensitization was 0%. No evidence of skin sensitization in guinea pigs was found.

Test Report

1 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

2 Reference

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

3 Compliance

Good Laboratory Practice Regulations, 21 CFR, Part 58.
ISO/IEC 17025:2017 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 Registration No. CNAS L2954.
RB/T 214—2017 Competence assessment for inspection body and laboratory mandatory approval—General requirements for inspection body and laboratory Certification and Accreditation Administration of the People's Republic of China INSPECTION BODY AND LABORATORY MANDATORY APPROVAL Certificate No. CMA 180015144061.

4 Identification of Test and Control Articles

4.1 Test Article

Test Article Name	Savewo ClassicMask
Manufacturer	Savewo Limited
Address	1/F, 266-270 Texaco Road, Tsuen Wan, Hong Kong
Test Article Initial State	Non-sterile
CAS Number	Not supplied by sponsor (N/S)
Model	ClassicMask
Size	175 x 95mm
Lot/Batch	Lot 21212280
Raw Material	N/S
Packaging Material	N/S
Physical State	Solid
Color	White
Density	N/S
Stability	N/S
Solubility	N/S
Storage Condition	Room temperature
Intended Use	Surgical Mask is intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganism, blood, body fluids, and particulate materials.Surgical Mask is intended for use in infection control practices to reduce potential exposure to blood and body fluids.
Additional Information	Lot 21212280

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

The Sponsor is responsible for all test article characterization data as specified in the GLP regulations.

4.2 Control Article

4.2.1 Negative Control

Name: Sesame oil (SO).
Manufacturer: Ji'an Lvyuan Natural perfume oil Refinery
Size: 5kg
Lot/ Batch#: 20211010
Physical State: Oily liquid
Color: Pale yellow
Storage Condition: Room Temperature

4.2.2 Positive Control

Name: 2, 4-Dinitrochlorobenzene (DNCB)
Manufacturer: Chengdu Aikeda Chemical Reagent Co., Ltd.
Size: 100g
Lot/ Batch#: 201904101
Induction Concentration: 0.5%
Challenge Concentration: 0.1%
Solvent: Sesame oil
Date prepared: Intradermal Induction Phase I :2021-11-15; Topical Induction Phase II: 2021-11-22; Challenge Phase: 2021-12-07
Physical State: Liquid
Color: Light Yellow
Storage Condition: Room Temperature

5 Equipment and Reagents

5.1 Equipment

Equipment Name	Equipment Number	Calibration Expire
Electronic scale	SDWH442	2022-04-06
Horizontal Large Capacity Constant Temperature Vibrator	SDWH2671	2022-11-25
Electronic Balance	SDWH2601	2022-05-11
Steel straight scale	SDWH463	2022-06-29
Vertical pressure steam sterilizer	SDWH2204	2022-03-09

5.2 Reagents

Reagent Name	Manufacturer	LOT
Freund's adjuvant, complete liquid	SIGMA	SLCG1631
Sodium dodecyl sulfate (SDS)	Sinopharm Chemical Reagent Co., Ltd	20210105

6 Identification of Test System

Species: Hartley guinea pig (Cavia Porcellus)
Number: 15 (10 test +5 negative control)
Sex: Male
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, test code and first treatment date, etc.
Animal identification: Stain with dyeing liquid
Cages: plastic cage
Acclimation period: 7 days under the same conditions as for the actual test

7 Animal Care and Maintenance

Animal source: Suzhou Experimental Animal Sci-Tech Co., Ltd. <Permit Code: SCXK (SU) 2020-0007>
Bedding: corncob, Suzhou Shuangshi Laboratory Animal Feed Science Co., Ltd.
Feed: guinea pig diet, Suzhou Experimental Animal Sci-Tech Co., Ltd.
Water: drinking water met the Standards for Drinking Water Quality GB 5749–2006
Animal room temperature: 18 ~ 26°C
Animal room relative humidity: 30% ~ 70%
Lights: 12 h 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, or bedding expected to interfere with the test data.

8 Justification of Test System and Route of Administration

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, 2,4-dinitrochlorobenzene (DNCB) has been substantiated at SDWH (listed in **Table 1** and **Table 2**).
The test article was extracted and administered in vivo through a medium compatible with the test system. Dermal application corresponds to the likely route of human exposure.

9 Experimental Design

9.1 Preparation of Extracts

9.1.1 Pretreatment

No pretreatment required.

9.1.2 Extraction

Under aseptic conditions, samples were taken according to the sampling method (Whole sampling, excluding the nose clip, add additional volume of extraction vehicle that the test sample absorbs when performing the extraction, using the data of the combined area of all tissue contacting surfaces of each sample provided by the sponsor as the standard surface area, 166.25 cm^2). The extraction was performed with agitation in closed inert containers according to the extraction ratio listed in the following table (sample: extraction vehicle). The extraction vehicle was SO.

Test Period	Actual Sampling	Extract Procedure			Final Extract
		Extract Ratio	SO	Condition	
Intradermal Induction Phase I	Surface area 166.25 cm^2	3 cm^2 : 1 mL	83.1 mL	50°C, 72 h	Clear
Topical Induction Phase II	Surface area 166.25 cm^2	3 cm^2 : 1 mL	83.1 mL	50°C, 72 h	Clear
Challenge Phase	Surface area 166.25 cm^2	3 cm^2 : 1 mL	83.1 mL	50°C, 72 h	Clear

The state of the extract did not change after extraction. The extract was stored at room temperature,

and tested within 24 h, without the process of adjusting its pH value, filtering, centrifuging, diluting, etc.
The vehicle (without the test article) was similarly prepared to serve as the control.

9.2 Experimental Procedure

9.2.1 Animal Preparation and Grouping

On the first day of treatment, 15 guinea pigs were weighed and identified. The fur from the dorsoscapular area of the animals was removed with an electric clipper. Grouping as follow:

Group Name	Group Size	Gender
Test	10 animals	Male
Negative Control	5 animals	Male

9.2.2 Intradermal Induction Phase I

A pair of 0.1 mL intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.
Site A: A 50:50 (*V*/*V*) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.
Site B: the test sample (undiluted extract); the control animals were injected with the solvent alone.
Site C: the test sample at the concentration used at site B, emulsified in a 50:50 (*V*/*V*) stable emulsion of Freund's complete adjuvant and the solvent (50%); inject the control animals with an emulsion of the blank liquid with adjuvant.

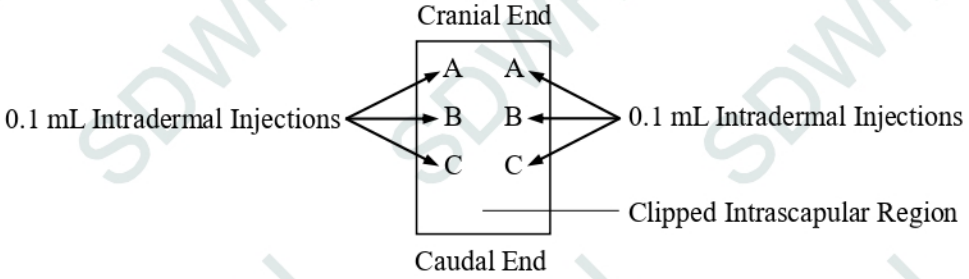

Figure 1 Locations of intradermal injection sites

9.2.3 Topical Induction Phase II

The maximum concentration that can be achieved in Intradermal induction phase I did not produce irritation. Animals are pretreated with 10% sodium dodecyl sulfate (Solvent: Distilled water, Date prepared: 2021-11-15) (24 ± 2) h before the topical induction application.
At 7 ± 1 d after completion of the intradermal induction phase, administer 0.5 mL test article extract by topical application to the intrascapular region of each animal, using a patch of area approximately 8 cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48 ± 2) h.
Treat the control animals similarly, using the blank liquid alone.

9.2.4 Challenge Phase

At 14 ± 1 d after completion of the topical induction phase, challenge all test and control animals with the test sample. Administer 0.5 ml test article extract and control article by topical application to sites that were not treated during the induction stage, using absorbent gauze (8 cm^2) soaked in the test article extract or control article. Secure with an occlusive dressing. Remove the dressings and patches after (24 ± 2) h.

9.3 Observation of Animals

Observe the appearance of the challenge skin sites of the test and control animals (24 ± 2) h and (48 ± 2) h after removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in the following table for each challenge site and at each time interval.

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

9.4 Evaluation of Results

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.

The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

10 Results

The results of skin reaction after challenge were listed in **Table 3**. No skin sensitization reaction was found in the skin of guinea pigs using extracts of the test article, and the positive rate of sensitization was 0%.

The positive rate of sensitization in the positive control group was 100%, listed in **Table 1**.

Clinical observations and weight changes of guinea pigs were listed in **Table 4.**

11 Conclusion

Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig.

12 Record Storage

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

13 Confidentiality Agreement

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

14 Deviation Statement

There were no deviations from the approved study protocol which were judged to have any impact on the validity of the data.

Annex 1 Test Data

Table 1 Guinea pig sensitization dermal reactions of positive control

Group	Animal Number	(24 ± 2) h Before Phase II Patch Application		(24 ± 2) h Following Challenge Phase		(48 ± 2) h Following Challenge Phase		Positive Rate after Challenge Phase
		Left	Right	Test Sites	Control Sites	Test Sites	Control Sites	
Positive Control	1	3	2	1	0	1	0	100%
	2	2	3	2	0	1	0	
	3	3	3	2	0	1	0	
	4	2	3	2	0	2	0	
	5	3	3	2	0	1	0	
Negative Control	6	0	0	0	0	0	0	-
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	

Note: the data of positive control come from SDWH- M202106058-2 (Completed Date: 2021-12-10)

Table 2 Weigh change and clinical observation of positive control

Group	Animal Number	Weight (g)		Clinical Observation Except Dermal Reactions
		Before Injection	After Experiment	
Positive Control	1	334	415	Normal
	2	333	410	Normal
	3	346	430	Normal
	4	341	417	Normal
	5	347	428	Normal
Negative Control	6	304	362	Normal
	7	335	414	Normal
	8	352	435	Normal
	9	321	394	Normal
	10	310	379	Normal

Note: the data of positive control come from SDWH- M202106058-2 (Completed Date: 2021-12-10)

Table 3 Guinea pig sensitization dermal reactions

Group	Animal Number	(24 ± 2) h Before Phase II Patch Application		(24 ± 2) h Following Challenge Phase		(48 ± 2) h Following Challenge Phase		Positive Rate after Challenge Phase
		Left	Right	Test Sites	Control Sites	Test Sites	Control Sites	
Test	1	0	0	0	0	0	0	0%
	2	0	0	0	0	0	0	
	3	0	0	0	0	0	0	
	4	0	0	0	0	0	0	
	5	0	0	0	0	0	0	
	6	0	0	0	0	0	0	
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	
Negative Control	11	0	0	0	0	0	0	-
	12	0	0	0	0	0	0	
	13	0	0	0	0	0	0	
	14	0	0	0	0	0	0	
	15	0	0	0	0	0	0	

Table 4 Weigh change and clinical observation

Group	Animal Number	Weight (g)		Clinical Observation Except Dermal Reactions
		Before Injection	After Experiment	
Test	1	335	417	Normal
	2	324	397	Normal
	3	307	368	Normal
	4	318	389	Normal
	5	337	411	Normal
	6	357	442	Normal
	7	314	377	Normal
	8	349	434	Normal
	9	355	446	Normal
	10	351	434	Normal
Negative Control	11	316	387	Normal
	12	315	379	Normal
	13	345	423	Normal
	14	334	416	Normal
	15	302	358	Normal

Annex 2 Photograph of Test Article

Annex 3 Information Provided by Sponsor

1 Production Process

Not supplied by sponsor.

2 Other Information

Not supplied by sponsor.

End of Report

180015144061

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TESTING
CNAS L2954

Final Report

Report Number: SDWH-M202106929-4(E)

Skin Irritation Test of Savewo ClassicMask

According to ISO 10993-10:2010
0.9% Sodium Chloride Injection Extract

Sponsor: Savewo Limited

Address: 1/F, 266-270 Texaco Road, Tsuen Wan, Hong Kong

Sanitation & Environment Technology Institute, Soochow University
Address: 199 Ren-Ai Road, Suzhou Industrial Park, Suzhou, Jiangsu 215123, P. R. China
Website: www.sudatest.com E-mail: med@sudatest.com
Direct: +86 512 65880038 Free: 400 107 8828

Content

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 inspection and 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 results relate only to the articles tested.

(5) The report shall not be reproduced except in full without the written approval of the institute.

Quality Assurance Statement

The Quality Assurance Unit inspected/audited this study in compliance with the following GLP regulations:
Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA).

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the Testing Facility Management. The final report was reviewed by the Quality Assurance Unit. The final report accurately describes the test methods in accordance with standard operating procedures, and the results are consistent with raw data of non-clinical studies conducted according to the study protocol.

Inspections	Date of Inspection	Date Reported to Study Director	Date Reported to Testing Facility Management.
Study Protocol	2021-12-17	2021-12-17	2021-12-28
Study Procedure	2021-12-21	2021-12-21	2021-12-28
Raw Data	2021-12-28	2021-12-28	2021-12-28
Final Report	2021-12-28	2021-12-28	2021-12-28

Quality Assurance Unit: Zou Jing 2021-12-28

Quality Assurance Date

GLP Compliance Statement

This study was fully in accordance with the technical requirements of the study protocol.

This study was conducted in compliance with Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA).

Verification Dates

Test Article Receipt	2021-12-15
Protocol Effective Date	2021-12-17
Technical Initiation Date	2021-12-17
Technical Completion Date	2021-12-24
Final Report Completion Date	2021-12-30

Edited by: Xu Yueyue 2021-12-28
Date

Reviewed by: 2021-12-30
Study Director Date

Approved by: Wang Lijie 2021-12-30
Authorized Signatory Date

Sanitation & Environment Technology Institute, Soochow University

Summary

1 Test Article

Test Article Name	Savewo ClassicMask
Manufacturer	Savewo Limited
Address	1/F, 266-270 Texaco Road, Tsuen Wan, Hong Kong
Model	ClassicMask
Lot/Batch	Lot 21212280

2 Main Reference

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

3 Test Method

The extract of test article was evaluated for skin irritation. With ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.
Study protocol number: SDWH-PROTOCOL- GLP-M202106929-4.

4 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.

Test Report

1 Purpose

The extract of test article was evaluated for skin irritation and extrapolating the results to humans, but it does not establish the actual risk of irritation.

2 Reference

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

3 Compliance

Good Laboratory Practice Regulations, 21 CFR, Part 58.
ISO/IEC 17025:2017 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 Registration No. CNAS L2954.
RB/T 214—2017 Competence assessment for inspection body and laboratory mandatory approval—General requirements for inspection body and laboratory Certification and Accreditation Administration of the People's Republic of China INSPECTION BODY AND LABORATORY MANDATORY APPROVAL Certificate No. CMA 180015144061.

4 Identification of Test and Control Articles

4.1 Test Article

Test Article Name	Savewo ClassicMask
Manufacturer	Savewo Limited
Address	1/F, 266-270 Texaco Road, Tsuen Wan, Hong Kong
Test Article Initial State	Non-sterile
CAS Number	Not supplied by sponsor (N/S)
Model	ClassicMask
Size	175 x 95mm
Lot/Batch	Lot 21212280
Raw Material	N/S
Packaging Material	N/S
Physical State	Solid
Color	White
Density	N/S
Stability	N/S
Solubility	N/S
Storage Condition	Room temperature
Intended Use	Surgical Mask is intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganism, blood, body fluids, and particulate materials.Surgical Mask is intended for use in infection control practices to reduce potential exposure to blood and body fluids.
Additional Information	Lot 21212280

The information about the test article was supplied by the sponsor wherever applicable.
The Sponsor is responsible for all test article characterization data as specified in the GLP regulations.

4.2 Control Article

4.2.1 Negative Control

Name: 0.9% sodium chloride injection (SC)
Manufacturer: Guangxi Yuyuan Pharmaceutical Co., Ltd.
Size: 500mL
Lot/ Batch#: H21062603
Physical State: Liquid
Color: Colourless
Storage Condition: Room Temperature

4.2.2 Positive Control

Name: sodium dodecyl sulfate
Manufacturer: Sinopharm Chemical Reagent Co., Ltd
Size: 500g
Lot/ Batch#: 20210105
Physical State: Powder
Color: White
Storage Condition: Room Temperature
Solvent: 0.9% sodium chloride injection (SC)
Concentration: 20%
Date prepared: 2021-06-22

5 Equipment and Reagents

5.1 Equipment

Equipment Name	Equipment Number	Calibration Expire
Electronic Scale	SDWH2436	2022-05-11
Horizontal constant temperature culture oscillator	SDWH2718	2022-07-21
Electronic Balance	SDWH2601	2022-05-11
Steel straight scale	SDWH463	2022-06-29
Vertical pressure steam sterilizer	SDWH2204	2022-03-09

5.2 Reagents

Reagent Name	Manufacturer	LOT
0.9% sodium chloride injection (SC)	Guangxi Yuyuan Pharmaceutical Co., Ltd.	H21062603
Sodium dodecyl sulfate (SDS)	Sinopharm Chemical Reagent Co., Ltd	20210105

6 Identification of Test System

Species: New Zealand white Rabbit (single strain).
Number: 3
Sex: Female
Weigh: 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 cages identified by a card indicating the lab number, test code and first treatment date.
Animal identification: Stain with dyeing liquid

Cages: Stainless steel cage
Acclimation Period: 7 days under the same conditions as for the actual test

7 Animal Care and Maintenance

Animal purchase: Provided by Suzhou Experimental Animal Sci-tech Co., Ltd. <Permit Code: SCXK (SU) 2020-0007>
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: 18-26°C
Animal room relative humidity: 30%-70%
Lights: 12hours 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 Justification of Test System and Route of Administration

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. Positive control sodium dodecyl sulfate has been substantiated at SDWH with this method. See table 3.
The patches (about 2.5cm×2.5cm) which moistened by test article extract, and directly applying to the rabbit skin is considered to be the best mean of contact.

9 Experimental Design

9.1 Preparation of Extracts

9.1.1 Pretreatment

No pretreatment required.

9.1.2 Extraction

Under aseptic conditions, samples were taken according to the sampling method (Whole sampling, excluding the nose clip, add additional volume of extraction vehicle that the test sample absorbs when performing the extraction, using the data of the combined area of all tissue contacting surfaces of each sample provided by the sponsor as the standard surface area, 166.25 cm^2). The extraction was performed with agitation in closed inert containers according to the extraction ratio listed in the following table (sample: extraction vehicle). The extraction vehicle was SC.

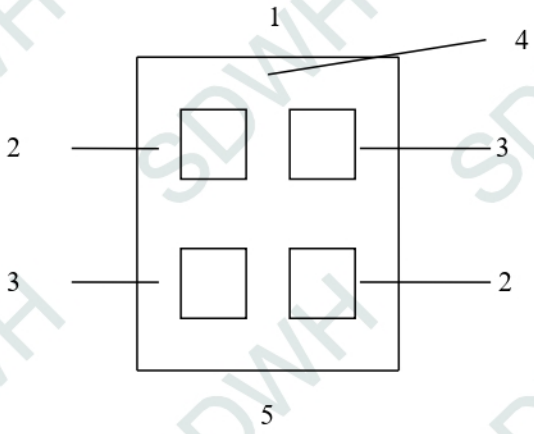
Test Period	Actual Sampling	Extract Procedure			Final Extract
		Extract Ratio	Extraction volume	Condition	
polar test extract	Surface area 166.25 cm^2	3 cm^2 : 1 mL	64.9 mL	50°C, 72 h	Clear
polar negative control	/	/	10.0 mL		Clear

The state of the extract did not change after extraction. The extract was stored at room temperature, and tested within 24 h, without the process of adjusting its pH value, filtering, centrifuging, diluting, etc. The vehicle (without the test article) was similarly prepared to serve as the control.

9.2 Experimental Procedure

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

Apply 0.5 mL extract (s) of test article or control to 2.5 cm×2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit as shown in Figure 1, and then wrap the application sites with a bandage (semi-occlusive or occlusive) for a minimum of 4 h. At the end of the contact time, remove the dressing and washing with lukewarm water or other suitable nonirritating solvent and careful drying.



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

Figure1 Location of skin application sites

9.3 Observation of Animals

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 — Scoring 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 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
Maximal possible score for irritation	8
Other adverse changes at the skin sites shall be recorded and reported.	

9.4 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 were totalled separately for each test sample and blank for each animal. 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).

To obtain the primary irritation index for the test article, 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.
The primary irritation index (PII) for the test article was evaluated according to Table 2.

Table 2 — Primary or cumulative irritation index categories in a rabbit

Mean score	Response category
0~0.4	Negligible
0.5~1.9	Slight
2~4.9	Moderate
5~8	Severe

10 Results

All animals were survived and no abnormal signs were observed during the study. According to what observed, the response of skin on testing side did not exceed that on the control side. Thus, the primary irritation index for the test article was calculated to be 0. See table 4.

11 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.

12 Record Storage

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

13 Confidentiality Agreement

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

14 Deviation Statement

There were no deviations from the approved study protocol which were judged to have any impact on the validity of the data.

Annex 1 Test Data

Table 3 Positive control

Extract	Rabbit No.	Group	Reaction	Interval (hours): score=left site/right site		
				24±2h	48±2h	72±2h
SC	1	Positive Control	Erythema	3/3	3/3	3/3
			Oedema	3/3	4/4	4/4
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SC	2	Positive Control	Erythema	3/3	3/3	3/3
			Oedema	3/3	3/4	4/4
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SC	3	Positive Control	Erythema	3/3	3/3	3/3
			Oedema	3/3	4/3	4/4
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
The primary irritation score.					6.6	

Note: Positive control performed once every six months, see SDWH-M202103118-1(Completed Date: 2021-06-25).

Table 4 Test Results of Dermal Observations

Extract	Rabbit No.	Group	Reaction	Interval (hours): score=left site/right site		
				24±2h	48±2h	72±2h
SC	1	Test Article	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SC	2	Test Article	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SC	3	Test Article	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
The primary irritation score.					0	

Annex 2 Photograph of Test Article

Annex 3 Information Provided by Sponsor

1 Production Process

Not supplied by sponsor.

2 Other Information

Not supplied by sponsor.

End of Report

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中国认可
国际互认
检测
TESTING
CNAS L2954

Final Report

Report Number: SDWH-M202106929-5(E)

Skin Irritation Test of Savewo ClassicMask

According to ISO 10993-10:2010
Sesame Oil Extract

Sponsor: Savewo Limited

Address: 1/F, 266-270 Texaco Road, Tsuen Wan, Hong Kong

Sanitation & Environment Technology Institute, Soochow University
Address: 199 Ren-Ai Road, Suzhou Industrial Park, Suzhou, Jiangsu 215123, P. R. China
Website: www.sudatest.com
E-mail: med@sudatest.com
Direct: +86 512 65880038
Free: 400 107 8828

Content

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 inspection and 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 results relate only to the articles tested.

(5) The report shall not be reproduced except in full without the written approval of the institute.

Quality Assurance Statement

The Quality Assurance Unit inspected/audited this study in compliance with the following GLP regulations:
Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA).

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the Testing Facility Management. The final report was reviewed by the Quality Assurance Unit. The final report accurately describes the test methods in accordance with standard operating procedures, and the results are consistent with raw data of non-clinical studies conducted according to the study protocol.

Inspections	Date of Inspection	Date Reported to Study Director	Date Reported to Testing Facility Management.
Study Protocol	2021-12-17	2021-12-17	2021-12-28
Study Procedure	2021-12-21	2021-12-21	2021-12-28
Raw Data	2021-12-28	2021-12-28	2021-12-28
Final Report	2021-12-28	2021-12-28	2021-12-28

Quality Assurance Unit: Zou Jing 2021-12-28

Quality Assurance Date

GLP Compliance Statement

This study was fully in accordance with the technical requirements of the study protocol.

This study was conducted in compliance with Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA).

Verification Dates

Test Article Receipt	2021-12-15
Protocol Effective Date	2021-12-17
Technical Initiation Date	2021-12-17
Technical Completion Date	2021-12-24
Final Report Completion Date	2021-12-30

Edited by: Xu Yueyue 2021-12-28
Date

Reviewed by: 2021-12-30
Study Director Date

Approved by: Wang Yijie 2021-12-30
Authorized Signatory Date

Sanitation & Environment Technology Institute, Soochow University

Summary

1 Test Article

Test Article Name	Savewo ClassicMask
Manufacturer	Savewo Limited
Address	1/F, 266-270 Texaco Road, Tsuen Wan, Hong Kong
Model	ClassicMask
Lot/Batch	Lot 21212280

2 Main Reference

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

3 Test Method

The extract of test article was evaluated for skin irritation. With ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.
Study protocol number: SDWH-PROTOCOL- GLP-M202106929-5.

4 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.

Test Report

1 Purpose

The extract of test article was evaluated for skin irritation and extrapolating the results to humans, but it does not establish the actual risk of irritation.

2 Reference

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

3 Compliance

Good Laboratory Practice Regulations, 21 CFR, Part 58.
ISO/IEC 17025:2017 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 Registration No. CNAS L2954.
RB/T 214—2017 Competence assessment for inspection body and laboratory mandatory approval—General requirements for inspection body and laboratory Certification and Accreditation Administration of the People's Republic of China INSPECTION BODY AND LABORATORY MANDATORY APPROVAL Certificate No. CMA 180015144061.

4 Identification of Test and Control Articles

4.1 Test Article

Test Article Name	Savewo ClassicMask
Manufacturer	Savewo Limited
Address	1/F, 266-270 Texaco Road, Tsuen Wan, Hong Kong
Test Article Initial State	Non-sterile
CAS Number	Not supplied by sponsor (N/S)
Model	ClassicMask
Size	175 x 95mm
Lot/Batch	Lot 21212280
Raw Material	N/S
Packaging Material	N/S
Physical State	Solid
Color	White
Density	N/S
Stability	N/S
Solubility	N/S
Storage Condition	Room temperature
Intended Use	Surgical Mask is intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganism, blood, body fluids, and particulate materials.Surgical Mask is intended for use in infection control practices to reduce potential exposure to blood and body fluids.
Additional Information	Lot 21212280

The information about the test article was supplied by the sponsor wherever applicable.
The Sponsor is responsible for all test article characterization data as specified in the GLP regulations.

4.2 Control Article

4.2.1 Negative Control

Name: sesame oil (SO)
Manufacturer: Ji'an Lvyuan Natural perfume oil Refinery
Size: 5kg
Lot/ Batch#: 20211010
Physical State: Oily liquid
Color: Pale yellow
Storage Condition: Room Temperature

4.2.2 Positive Control

Name: sodium dodecyl sulfate
Manufacturer: Sinopharm Chemical Reagent Co., Ltd
Size: 500g
Lot/ Batch#: 20210105
Physical State: Powder
Color: White
Storage Condition: Room Temperature
Solvent: Sesame Oil
Concentration: 20%
Date prepared: 2021-06-22

5 Equipment and Reagents

5.1 Equipment

Equipment Name	Equipment Number	Calibration Expire
Electronic Scale	SDWH2436	2022-05-11
Horizontal constant temperature culture oscillator	SDWH2718	2022-07-21
Electronic Balance	SDWH2601	2022-05-11
Steel straight scale	SDWH463	2022-06-29
Vertical pressure steam sterilizer	SDWH2204	2022-03-09

5.2 Reagents

Reagent Name	Manufacturer	LOT
Sesame oil (SO)	Ji'an Lvyuan Natural perfume oil Refinery	20211010
Sodium dodecyl sulfate (SDS)	Sinopharm Chemical Reagent Co., Ltd	20210105

6 Identification of Test System

Species: New Zealand white Rabbit (single strain).
Number: 3
Sex: Female
Weigh: 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 cages identified by a card indicating the lab number, test code and first treatment date.
Animal identification: Stain with dyeing liquid
Cages: Stainless steel cage

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

7 Animal Care and Maintenance

Animal purchase: Provided by Suzhou Experimental Animal Sci-tech Co., Ltd. <Permit Code: SCXK (SU) 2020-0007>
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: 18-26°C
Animal room relative humidity: 30%-70%
Lights: 12hours 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 Justification of Test System and Route of Administration

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. Positive control sodium dodecyl sulfate has been substantiated at SDWH with this method. See table 3.
The patches (about 2.5cm×2.5cm) which moistened by test article extract, and directly applying to the rabbit skin is considered to be the best mean of contact.

9 Experimental Design

9.1 Preparation of Extracts

9.1.1 Pretreatment

No pretreatment required.

9.1.2 Extraction

Under aseptic conditions, samples were taken according to the sampling method (Whole sampling, excluding the nose clip, add additional volume of extraction vehicle that the test sample absorbs when performing the extraction, using the data of the combined area of all tissue contacting surfaces of each sample provided by the sponsor as the standard surface area, 166.25 cm^2). The extraction was performed with agitation in closed inert containers according to the extraction ratio listed in the following table (sample: extraction vehicle). The extraction vehicle was SO.

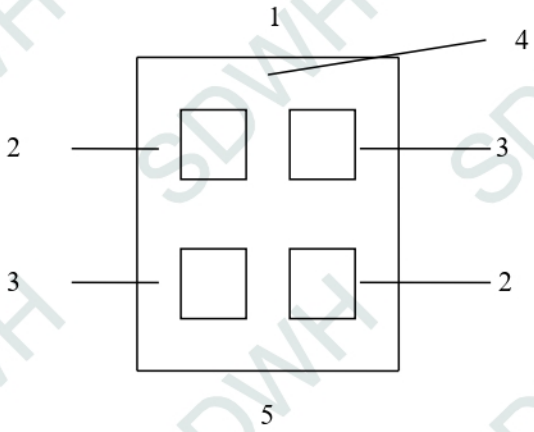
Test Period	Actual Sampling	Extract Procedure			Final Extract
		Extract Ratio	Extraction volume	Condition	
Non-polar test extract	Surface area 166.25 cm^2	3 cm^2 : 1 mL	83.1 mL	50°C, 72 h	Clear
Non-polar negative control	/	/	10.0 mL		Clear

The state of the extract did not change after extraction. The extract was stored at room temperature, and tested within 24 h, without the process of adjusting its pH value, filtering, centrifuging, diluting, etc. The vehicle (without the test article) was similarly prepared to serve as the control.

9.2 Experimental Procedure

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

Apply 0.5 mL extract (s) of test article or control to 2.5 cm×2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit as shown in Figure 1, and then wrap the application sites with a bandage (semi-occlusive or occlusive) for a minimum of 4 h. At the end of the contact time, remove the dressing and washing with lukewarm water or other suitable nonirritating solvent and careful drying.



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

Figure1 Location of skin application sites

9.3 Observation of Animals

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 — Scoring 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 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
Maximal possible score for irritation	8
Other adverse changes at the skin sites shall be recorded and reported.	

9.4 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 were totalled separately for each test sample and blank for each animal. 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).

To obtain the primary irritation index for the test article, 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.
The primary irritation index (PII) for the test article was evaluated according to Table 2.

Table 2 — Primary or cumulative irritation index categories in a rabbit

Mean score	Response category
0~0.4	Negligible
0.5~1.9	Slight
2~4.9	Moderate
5~8	Severe

10 Results

All animals were survived and no abnormal signs were observed during the study. According to what observed, the skin reaction of non-polar extract on testing side did not exceed that on the control side. Thus, the final test article score was calculated to be 0. See table 4.

11 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.

12 Record Storage

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

13 Confidentiality Agreement

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

14 Deviation Statement

There were no deviations from the approved study protocol which were judged to have any impact on the validity of the data.

Annex 1 Test Data

Table 3 Positive control

Extract	Rabbit No.	Group	Reaction	Interval (hours): score=left site/right site		
				24±2h	48±2h	72±2h
SO	1	Positive Control	Erythema	3/3	3/3	3/4
			Oedema	3/3	3/3	3/4
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SO	2	Positive Control	Erythema	3/3	3/3	3/4
			Oedema	3/3	4/3	4/4
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SO	3	Positive Control	Erythema	3/3	3/3	4/3
			Oedema	3/3	3/4	3/4
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
The primary irritation score.					6.5	

Note: Positive control performed once every six months, see SDWH-M202103118-2(Completed Date: 2021-06-25).

Table 4 Test Results of Dermal Observations

Extract	Rabbit No.	Group	Reaction	Interval (hours): score=left site/right site		
				24±2h	48±2h	72±2h
SO	1	Test Article	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SO	2	Test Article	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SO	3	Test Article	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
The primary irritation score.					0	

Annex 2 Photograph of Test Article

Annex 3 Information Provided by Sponsor

1 Production Process

Not supplied by sponsor.

2 Other Information

Not supplied by sponsor.

End of Report