CoShield GLOBAL

Face Mask Non-Sterile Type IIR

September 2020 - Draft v1

CoShield GLOBAL

Face Mask Non-Sterile Type IIR

Technical Data Sheet

Device variants:

- Type IIR: Disposable Mask with elastic ear loops.
- EN14683:2019
- Ref: DS02

Measurements:

Item:	Dimensions:	Information:
Mask:	Length	175 +/-
	Width (pleated)	95 +/-
Loop:	Length	175 +/-

Technical Features :

Performance:	Information: Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 98%
Differential pressure (Pa/cm²)	< 60
Splash resistance (kPa)	≥ 16,0

- Shelf life: 2 years
- Storage: Protect from sunlight, dust and humidity
- Usage: Single use
- Sterilization: Non- Sterile
- Applied standards: EN 14683:2019, CE class 1
- Product classification: Medical device acc. to MDD 93/42/EEC.

CoShield GLOBAL

Face Mask Non-Sterile Type IIR

Material Data:

Section:	Item:	Information:
Inner layer:	Material	Polypropylene (PP) Non-woven
	Weight/m²	25 g
	Colour	White
Outer layer:	Material	Polypropylene (PP) Non-woven
	Weight/m²	25 g
	Colour	Blue
Filter media:	Material	Melt-blown
	Weight/m²	25 g
	Colour	White
Nose piece:		Pliable encapsulated
Free of:		Glass fibres, latex, additives

IMPORTANT NOTICE:

This guide is only an outline. It should not be used as the only means for selecting protective clothing. Before using any protective clothing, the wearer must read and understand the user instructions for each product.
Specific country legislation must be observed. If in doubt, contact a safety professional. Selection of the most appropriate PPE will depend on the particular situation and should only be make a competent person knowledgeable of the actual working conditions and the limitations of PPE.
Final determination as to the suitability of these products for a particular situation is the employer's responsibility.
This information is subject to revision at any time. Always read and follow instructions.

LIMITATION OF LIABILITY:

Except as provided above, Dishang Medical shall not be liable or responsible for any loss or damage, whether direct, indirect, incidental, special or consequential arising out of the sale, use or misuse of this product, or the user's inability to use such products.

CoShield Global Ltd.
Exchange Place,
Poseidon way,
Warwick,
CV34 6BY
UK

Email: unitedkingdom@coshield.com

Telephone: 03300555540

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All data refer to typical single values and may be subject to alterations.

CE

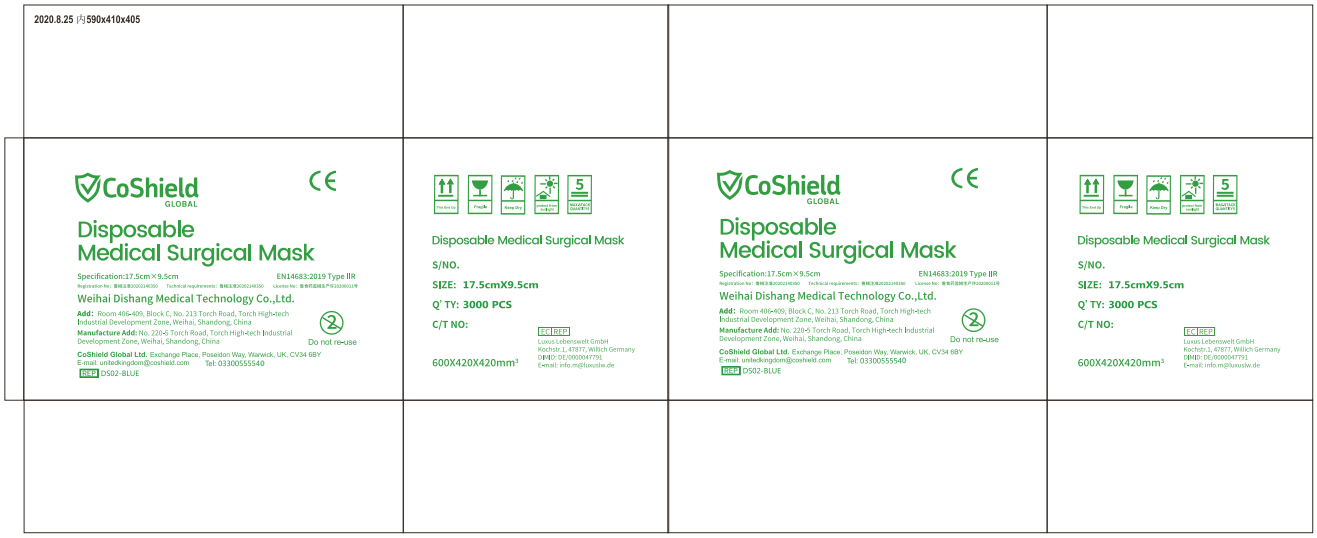
Package Information of Disposable Medical Surgical Mask

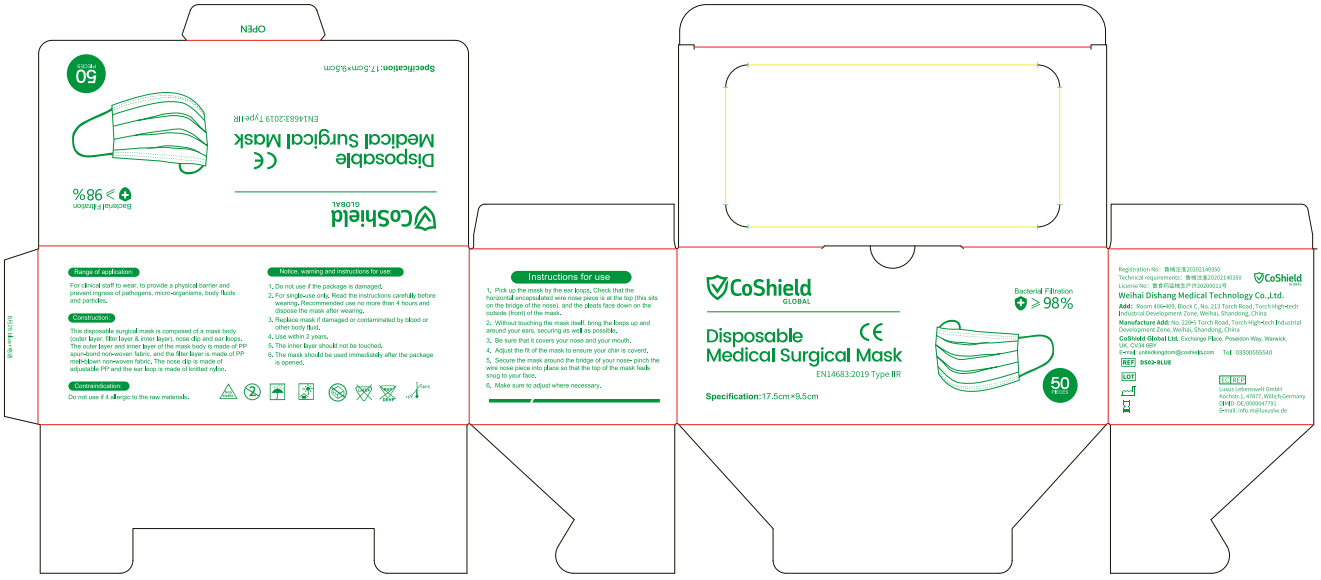
Box size :L19.5cmX 10cm X 8cm

50PCS/inner bag , 1 pre-pack /box , 60 boxes in one ctn

3000 pcs /ctn Gross Weight : 14.1KG
Net Weight :12.74kg

Ctn size :L60cmX 42 cm X 42cm





CoShield GLOBAL

Registration No:鲁械注准20202140350
Technical requirements:鲁械注准20202140350
License No:鲁食药监械生产许20200011号

CE

Disposable Medical Surgical Mask
Instructions

⚠ Please read the manual carefully before use
Standard： EN14683:2019 Type IIR

Product Name: Disposable Medical Surgical Mask
REF: DS02-BLUE
Specifications: 17.5cmX9.5cm
Texture of material: This disposable surgical mask is composed of a mask body (outer layer, filter layer & inner layer), nose clip and ear loops. The outer layer and inner layer of the mask body is made of PP spun-bond non-woven fabric, and the filter layer is made of PP melt-blown non-woven fabric. The nose clip is made of adjustable PP and the ear loop is made of knitted nylon.
Date of manufacture: See package

Range of application:
For clinical staff to wear, to provide a physical barrier and prevent ingress of pathogens, microorganisms, body fluids and particles.

Construction:
This disposable surgical mask is composed of a mask body (outer layer, filter layer & inner layer), nose clip and ear loops. The outer layer and inner layer of the mask body is made of PP spun-bond non-woven fabric, and the filter layer is made of PP melt-blown non-woven fabric. The nose clip is made of adjustable PP and the ear loop is made of knitted nylon.

Contraindication:
Do not use if it allergic to the raw materials.

Notice,warning and instruction for use :
1. Do not use if the package is damaged.
2. For single-use only. Read the instructions carefully before wearing. Recommended use no more than 4 hours and dispose the mask after wearing.
3. Replace mask if damaged or contaminated by blood or other body fluid.
4. Use within 2 years.
5. The inner layer should not be touched.
6. The mask should be used immediately after the package is opened.

Instructions for use :
1. Pick up the mask by the ear loops. Check that the horizontal encapsulated wire nose piece is at the top (this sits on the bridge of the nose), and the pleats face down on the outside (front) of the mask.
2. Without touching the mask itself, bring the loops up and around your ears, securing as well as possible.
3. Be sure that it covers your nose and your mouth.
4. Adjust the fit of the mask to ensure your chin is coverd.
5. Secure the mask around the bridge of your nose- pinch the wire nose piece into place so that the top of the mask feels snug to your face.
6. Make sure to adjust where necessary.

⩾98%
Bacterial Filtration

Non sterile | Keep away from sunlight | Keep dry | Do not reuse | Latex free | DEHP free | -5°C +30°C

Manufacture: Weihai Dishang Medical Technology Co.,Ltd.

Add: Room 406-409, Block C, No. 213 Torch Road, Torch High-tech Industrial Development Zone, Weihai, Shandong, China
Manufacture Add: No. 220-5 Torch Road, Torch High-tech Industrial Development Zone, Weihai, Shandong, China

CoShield
2020. 08. 25

威海迪尚医疗科技有限公司
Weihai Dishang Medical Technology Co.,Ltd.

CE

产品合格证
Quality Certificate

CoShield GLOBAL

Registration No 注册证号：鲁械注准20202140350
Technical requirements 产品技术要求编号：鲁械注准20202140350
License No 生产许可证编号：鲁食药监械生产许20200011号

产品名称 Name	一次性使用医用外科口罩 Disposable medical surgical Mask
货　号 REF	DS02-BLUE
规格型号 Specification	型号：非无菌耳挂式 规格：17.5cmX9.5cm Non Sterile Ear-Hanging Spec:17.5cm X9.5cm
执行标准 Standard	EN14683:2019 Type IIR
生产批号 Batch No.	批
生产日期 product date	
有 效 期 Expiry Date	二年 Two years
检 验 员 Inspector	
产　地 Place of Origin	中国 China
生产厂商 Manufacturer	威海迪尚医疗科技有限公司 Weihai Dishang Medical Technology Co.,Ltd.
地　址: 威海市火炬高技术产业开发区火炬路220-5号 **Add:** No. 220-5, Torch Road, Torch High-tech Industrial Development Zone, Weihai, Shandong, China	
成　分: 70%聚丙烯纺粘无纺布；30%聚丙烯熔喷无纺布。 **Components:** 70% polypropylene spun-bond non-woven fabric; 30% polypropylene melt-blown non-woven fabric.	

威海迪尚医疗科技有限公司 QC 验收合格 02 检验部

MADE IN CHINA

Registration Notification

Reference Number: JH-ERA-20475VOO
Issued Date: May 18, 2020

This notification will be automatically void if the Notification is rejected by the EU Authorities or upon termination of the EAR.

This is notice that, According to Medical Device 93/42/EEC(MDD), we accepted the appointment to be the Authorized European Representative for products which listed in the attached agreement between below manufacturer and Luxus Lebenswelt GmbH.

Manufacturer: Weihai Dishang Medical Technology CO.,Ltd
Address: Room 406-409,Block C,No.213 Torch Road,Torch High-tech Industrial Development Zone,Weihai,Shandong Province,China

The Manufacturer declared that the Medical Device complies with the all essential requirements of Medical Device Directive 93/42/EEC(MDD).
According to Medical Device Directive 93/42/EEC(MDD), the European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011, the German Competent Authority is notified of the Manufacturer's Medical Devices shown as:

Disposable medical Mask,Disposable medical surgical Mask
UMDN code: 15-230
Registriernummer / Registration number：DE/CA20/01-Luxuslebenswelt-318/20

Where the manufacturer affixes the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) and standards have and continue to be met.

Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany
info.m@luxuslw.de

DISHANG

EC DECLARATION OF PRODUCT CONFORMITY

Dishang Medical, manufacturer of the below referenced product hereby declares that the product:

DS02 Blue Surgical Face Masks Type IIR

Is in conformity with the provisions of European Medical Devices Directive (MDD) 93/42/EEC and, where such is the case, with the national transposing harmonised standard:
EN 14683: 2019 (Type IIR)
As issued by -

SGS-CSTC Standard Technical Services (Shanghai) Co. Ltd
3rd Building No. 889
Yishan Road
Xuhui District
Shanghai
China

Certificate Number: SL52025233855601TX

The Technical Construction file is maintained by Dishang Medical, The Dishang Group 186 West Wenhua Road, Weihai, Shandong, 264209, China.

The product referenced above is identical to the model which is the subject of the EC Certificate issued by:

Weihai Dishang Medical Technology Co. Ltd
Room 406-409, Block C
No. 213 Torch Road
Torch High-Tech Industrial Development Zone
Weihai
Shandong
China

And further states that it is issued under the sole responsibility of Weihai Dishang Medical Technology Co Limited.

Completed at: Dishang Medical, The Dishang Group, 186 West Wenhua Road, Weihai, Shandong, 264209, China.

Eric Wei
Director

Issue Date: 13.05.2020

中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report SL52025233855601TX Date:April 20,2020 Page 1 of 3

WEIHAI DISHANG MEDICAL TECHNOLOGY CO.,LTD
ROOM 406-409, BLOCK C, NO.213 TORCH ROAD, TORCH HIGH-TECH INDUSTRIAL DEVELOPMENT ZONE, WEIHAI, SHANDONG CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Disposable medical surgical mask(Claimed Type IIR)
Sample Color	:	(A)white
Style No.	:	DS01-WHITE/DS02-BLUE
Proposed Care Instruction	:	-
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Mar 30,2020 & Apr 02,2020
Testing Period	:	Mar 31,2020 - Apr 20,2020
Test Result(s)	:	For further details, please refer to the following page(s).

Comment:

Medical Face Masks-Requirements and Test Methods(EN 14683:2019)	(A)
Clause 5.2.2 Bacterial filtration efficiency (BFE)	M
Clause 5.2.3 Breathability	M
Clause 5.2.4 Splash Resistance	M
Clause 5.2.5 Microbial Cleanliness	M

Remark: M=Meet EN 14683:2019 Type IIR requirement

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

Test Result

Medical Face Masks-Requirements and Test Methods
(EN 14683:2019)

Clause 5.2.2 Bacterial filtration efficiency (BFE)@**

	1#	2#	3#	4#	5#
(BFE), %	99.6	99.9	99.8	99.7	99.6

Remark: Performance Requirement: Type I>95%, Type II>98%, Type IIR >98%
**: The test was carried out by external laboratory assessed as competent
@: These test methods are not in CNAS accredited scope

Clause 5.2.3 Breathability
(EN 14683 :2019 Annex C, Flow rate 8 l/min)

Sample: A

	1#	2#	3#	4#	5#
Differential pressure △P (Pa/cm²)	32.7	29.4	30.1	28.7	26.5

Remark: Performance Requirement: Type I<40 Pa/cm², Type II<40 Pa/cm², Type IIR<60 Pa/cm²

Clause 5.2.4 Splash Resistance
(ISO 22609 :2004, Pressure 16.0 kPa)

Sample: A

Penetration on inside surface

1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Number of Pass: 32
Overall result: Acceptable

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR:≥16.0kPa
2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results

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Clause 5.2.5 Microbial Cleanliness
(EN 14683: 2019 Annex D)

	1#	2#	3#	4#	5#
CFU/g	<1	<1	<1	<1	<1

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
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CMA 180015344189

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Test Report

Report Number: SSMT-R-2020-01188-01

Sample Name: Disposable medical surgical Mask

Study Title: In Vitro Cytotoxicity Test

Standard: ISO 10993-5:2009

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

Weihai Dishang Medical Technology CO., Ltd

Room 406-409, Block C, No.213 Torch Road, Torch High-tech Industrial Development Zone, Weihai, Shandong China

Contents

Report No.:SSMT-R-2020-01188-01

Explanation

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full, without approval of the laboratory.

Conclusion

The study was to investigate the potential cytotoxicity of the test sample. The extract of the test article was added to L-929 cells and then incubated at 37℃ in 5% CO_2 for 24 hours. After the incubation, observe the cell morphology. The results were detected with MTT method. The results showed that the cytotoxicity ratio of the 100 % test article extract was 84.5% and the results of control groups showed the test was valid.

Under the conditions of this study, the extract of the test article did not show potential toxicity to L-929 cells.

Report No.:SSMT-R-2020-01188-01

Study verification and signature

The study was carried out in accordance with the standard operating procedure. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (IDT ISO/IEC 17025:2017) and RB/T 214-2017.

Date Received	2020-05-07
Technical Initiation Date	2020-05-19
Technical Completion Date	2020-05-21
Final Report Completion Date	2020-05-25

Edited by Cindy 2020.05.25 Date

Checked by Bella 2020.05.25 Date

Approved by Daisy 2020.06.12 Date
Authorized signatory

Jiangsu Science Standard Medical Testing Co., Ltd.

1.0 Purpose

The purpose of the test is to determine the potential cytotoxicity toxicity of a mammalian cell culture (mouse fibroblast L-929 cells) in response to the test article.

2.0 Standard

Biological evaluation of medical devices Part 5: Tests for In Vitro Cytotoxicity (ISO 10993-5:2009)

Biological evaluation of medical devices Part 12: Sample preparation and reference materials (ISO 10993-12:2012)

3.0 Test and control articles

3.1 Test article (The information about the test article was supplied by the sponsor wherever applicable.)

Test article name: Disposable medical surgical Mask

Sterilization state: Not sterilized

Model: DS01-WHITE/DS02-BLUE

Size: N/S

Lot/ Batch#: N/S

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

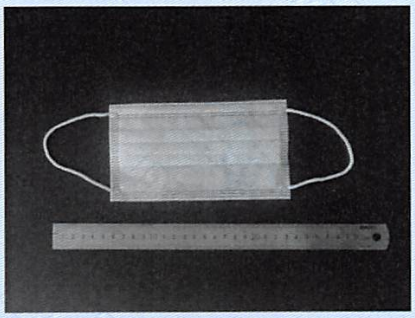
Solubility: N/S

Test Article Material: N/S

Packing Material: N/S

Storage Condition: Room temperature

Sample photograph:



3.2 Control Articles

3.2.1 Negative Control Article Name: High Density Polyethylene

Manufacturer: Jiangsu haiaosihui biotechnology co., LTD.

Size: 1.6 mm thick, 300*300 mm

Lot/ Batch#: M02F017

Physical State: Solid

Color: White

Storage Conditions: Room temperature

3.2.2 Positive Control Article Name: ZDEC

Manufacturer: Tokyo Into Industrial Co., Ltd.

Size: 25 g

Lot/ Batch#: DUDQG-JF

Physical State: Solid

Color: White

Storage Condition: Room temperature

Concentration: 0.1%

3.2.3 Blank Control Name: MEM medium, with addition 10% FBS

Physical State: Liquid

Color: Pink

Storage Condition: 4 ℃

4.0 Identification of test system

Mouse fibroblast L-929 cells obtained from ATCC CCL1 (NCTC clone 929).

5.0 Justification of test system

5.1 Historically, mouse fibroblast L-929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable cytotoxic articles.

5.2 The test article was extracted and administered in vitro to mouse fibroblast L-929 cells through a solvent compatible with the test system. This was the optimal route of administration available in this test system as recommended in the standard.

6.0 Instruments and Reagents

6.1Instruments

CO_2 Incubator (SSMT-279)

Biological microscope（SSMT-278）

Clean bench (SSMT-028)

Bench type low speed centrifuge (SSMT-048)

Vapour-bathing Constant Temperature Vibrator (SSMT-004)

Electronic balance (SSMT-015)

Steel Straight Scale (SSMT-072)

Multiskan Spectrum Microplate Spectrophotometer (SSMT-139)

Mini Vibrator (SSMT-311)

6.2 Reagents

FBS

MEM

Trypsin

Penicillin, Streptomycin sulfate

PBS

MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyletrazolium bromide)

Isopropyl alcohol

7.0 Experiment design and dose

7.1 Sample preparation

Aseptic extracting the test article (test article to volume of vehicle) according to the table below. Sealed and incubated in Vapour-bathing Constant Temperature Vibrator at 37 ℃ and 60 rpm for 24 hours. After the extraction, check the extraction changes, and immediately use for the experiment, the leach was not filtered, centrifuged or diluted. No pH adjustment.

Table 1 Sample preparation

Sampling		Aseptic Agitation Extraction In Inert Container				Final Extract
Sampling Manner	Actually sampling	Extraction solvent	Extraction ratio	Solvent volume	Condition	Clear or Not
Random sampling	18.0 cm^2	MEM medium (10% FBS)	3 cm^2 : 1 ml	6.0 ml	37 ℃, 24 h	Clear

The blank control (MEM medium, with addition 10% FBS) and negative/positive controls were prepared in the same condition.

7.2 Test method

Aseptic procedures were used for handling cell cultures.

L-929 cells were cultured in MEM medium (10% FBS, Penicillin 100 U/ml, Streptomycin sulfate 100 μg/ml) at 37℃ in a humidified atmosphere of 5% CO_2, then digested by 0.25% trypsin containing EDTA to get single cell suspension. And obtain a 1×10^5 cells/ml suspension by centrifuging (200 g, 3 min) and re-dispersing in MEM medium finally.

The suspended cells were dispensed at 100 μl per well in 96-well plate, and cultured in cell incubator (5% CO_2, 37℃, >90%humidity). Cell morphology was evaluated to verify that the monolayer was satisfactory.

After the cells grew to form a monolayer, original culture medium was discarded. The 96-well plates were then treated with 100 μl of extract of test article (100%, 75%, 50%, 25%), control article, negative article (100%) and positive article (100%) respectively. The 96-well plate was incubated at 37℃ in cell incubator of 5% CO_2 for 24 h. Six replicates of each test were tested.

After 24 h incubation, observe the cell morphology first and then discard the culture medium. A 50 μl aliquot of MTT (1 mg/ml) was added to each well and then incubated at 37℃ in a humidified atmosphere of 5% CO_2 for 2 hours. The liquid in each well was tipped out and 100 μl isopropanol was added to each well to suspend the cell layer. The microporous plate was vibrated for 10 min and monitored by the optical density at 570 nm on the microplate analyzer.

7.3 Statistical method

Mean±standard deviation（$\bar{x}$±s）

Viab. %=100×OD_{570e}/OD_{570b}

Where: OD_{570e}——is the mean value of the measured optical density of test sample/negative control/positive control;

OD_{570b}——is the mean value of the measured optical density of the blanks.

7.4 Observation of the cell morphology

Table 2 Observation of the cell morphology

Grade	Conditions of all cultures
0	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
1	Not more than 20 % of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Not more than 50 % of the cells are round, devoid of intracytoplasmatic granules, no extensive cell lysis; not more than 50 % growth inhibition observable.
3	Not more than 70 % of the cell layers contain rounded cells or are lysed; cell layers not completly destroyed, but more than 50 % growth inhibition observable.
4	Nearly complete or complete destruction of the cell layers.

8.0 Evaluation criteria

8.1 The 50% extract of the test article should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated.

8.2 The lower the Viab.% value, the higher the cytotoxic potential of the test article is.

8.3 If viability is reduced to < 70% of the blank, it has a cytotoxic potential.

8.4 The Viab.% of the 100% extract of the test article is the final result.

9.0 Results of the test

Table 3 Results of the cell vitality

Group	$\bar{x}$±s	Viability%	The morphology of the extracted cells was observed under the microscope
Blank control	0.523±0.042	100.0	0
Negative control	0.523±0.010	99.9	0
Positive control	0.013±0.004	2.5	4
100% test article extract	0.442±0.021	84.5	0
75% test article extract	0.469±0.019	89.6	0

50% test article extract	0.494±0.029	94.5	0
25% test article extract	0.519±0.015	99.2	0
Quality check	The mean OD_{570} of blanks is ≥ 0.2. The left (row2) and the right (row11) mean of the blanks do not differ by more than 15 %. The test meets the acceptance criteria.		
Conclusion	Under the conditions of this study, the test article did not show potential toxicity to L-929 cells.		

10.0 Deviation statement

There was no deviation from the approved standard operating procedure which were judged to have any impact on the validity of the data.

11.0 Record

All the original data and records related to this test and copies of the final report are retained in the archives of Science Standard Medical Testing.

12.0 Confidentiality agreement

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

CMA 180015344189

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Test Report

Report Number: SSMT-R-2020-01188-02

Sample Name: Disposable medical surgical Mask

Study Title: Skin Irritation Test

Standard: ISO 10993-10:2010

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

Weihai Dishang Medical Technology CO .,Ltd

Room 406-409, Block C, No.213 Torch Road, Torch High-tech Industrial Development Zone, Weihai, Shandong, China

Contents

Report No.: SSMT-R-2020-01188-02

Explanation

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.
6. This experiment was carried out in the sub-site and the address is: No. 68, Yaoluo Road, Wujin District, Changzhou City.

Conclusion

The animal skin irritation test was conducted to assess the potential irritation of the test article or material.

The test sample was extracted with 0.9% sodium chloride injection and sesame oil, respectively. The patches (about 2.5 cm×2.5 cm) which moistened by 0.5 ml extract of test article were directly applied to the rabbit skin for 4 hours. Observation for erythema and edema were conducted at 1 h, 24 h, 48 h and 72 h after removal of the patches.

The primary irritation indexes of the polar and non-polar test group were both calculated to be 0. The test result showed that the extract of the test article did not induce skin irritation in rabbit under the test condition.

Report No.: SSMT-R-2020-01188-02

Study verification and signature

The study was carried out in accordance with the standard operating procedure. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (ISO/IEC 17025:2017, IDT) and RB/T 214-2017.

Date Received	2020-05-07
Technical Initiation Date	2020-06-08
Technical Completion Date	2020-06-11
Final Report Completion Date	2020-06-11

Edited by Molly 2020.06.11 Date

Checked by Suri 2020.06.11 Date

Approved by Daisy 2020.06.12 Date

Authorized signatory

Jiangsu Science Standard Medical Testing Co., Ltd.

1.0 Purpose

New Zealand rabbits were used to evaluate the potential of skin irritation of samples under the condition of this test.

2.0 Reference

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

Biological evaluation of medical devices-Part 12:Sample preparation and reference materials(ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

3.0 Test and control articles

3.1 Test article (The information about the test article was supplied by the sponsor wherever applicable.)

Test article name: Disposable medical surgical Mask

Sterilization state: Unsterilized

Model: DS01-WHITE/DS02-BLUE

Size: N/S

Lot/ Batch#: N/S

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

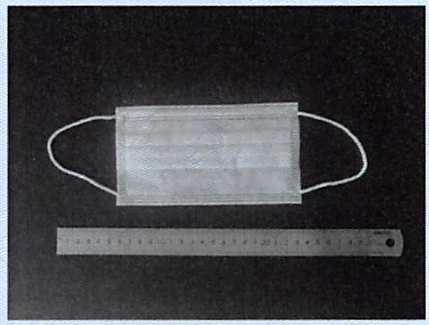
Solubility: N/S

Test Article Material: N/S

Packing Material: N/S

Storage Condition: Room Temperature

Sample photograph:



3.2 Control Articles

3.2.1 Polar Negative Control: 0.9% Sodium chloride injection (SC)

Manufacturer: Chenxin Pharmaceutical Co., Ltd.

Size: 250 ml

Physical State: Liquid

Color: Colourless

Lot/ Batch#: 1906112830

Storage Condition: Room Temperature

3.2.2 Non-polar Negative Control: Sesame Oil (SO)

Manufacturer: Ji'an lvyuanxiangliao. Co., Ltd.

Size: 20 kg

Physical State: Liquid

Color: Pale yellow

Lot/ Batch#: 20190516

Storage Condition: Room Temperature

4.0 Identification of test system

Species: New Zealand white rabbit (single strain)

Number: 6 (3 for polar test group and 3 for non-polar group)

Sex: Female

Weight: Initial body weight not less than 2.0 kg

Health status: Healthy, young adult, nulliparous and not pregnant.

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

Animal identification: Cage card

The quarantine period: 5 days

5.0 Animal Care and Maintenance

Animal purchase: Provided by Tongxiang Yinhai Animal Husbandry Professional Cooperative <Permit Code: SCXK (ZHE) 2018-0002>

Bedding: NA

Feed: Rabbit Diet, Beijing Keao Xieli Feed Co., Ltd.

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

Cages: Stainless steel cage, Suzhou Fengqiao purification equipment Co.,Ltd.

Environment: Temperature 16-26℃, Relative humidity 40%-70%, Lights 12 hours light/dark cycle

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy animals were selected

Veterinarian: Vet takes care of the whole course

Ethics: Test methods of operation were reviewed and approved by the Commission on Science Standard animal ethics

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

6.0 Justification of the test system

6.1 The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current

testing standards. Positive control 15% sodium dodecyl sulfate has been substantiated at SSMT with this method. Positive control tests are conducted every six months. The last irritation index of polar test group was 6.0. The last irritation index of non-polar test group was 5.7. The data was from the report SSMT-R-2020-01262-01 (Date: 2020-05-29).

6.2 The test article extract was directly applied to the rabbit skin, which was suggested by the standard.

7.0 Instruments

Digital oscillation incubator (SSMT-300)

Electronic balance (SSMT-075)

Clean bench (SSMT-187)

Straight steel ruler (SSMT-210)

8.0 Experiment design and dose

8.1 Sample preparation

The test article was extracted as Table 1. Extract was checked and used immediately after extraction without the process of filtering, centrifugation, dilution, etc. The pH of the extract was not adjusted prior to testing. The preparation process was aseptic. The control article was prepared under the same condition.

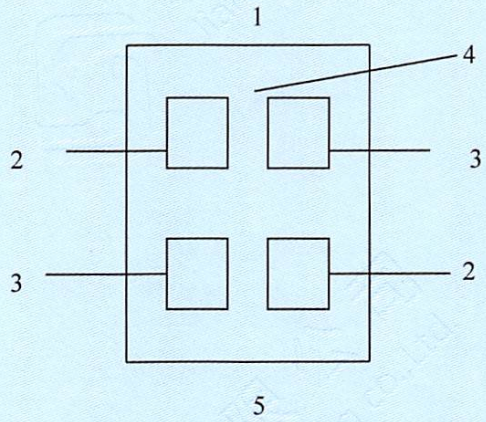
Table 1 Sample Preparation

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container				Final Extract
Sampling Manner	Actually Sampling	Extraction solvent	Extraction ratio	Solvent volume	Condition	Clear or Not
Random sampling	30.0 cm^2	0.9% sodium chloride injection	3 cm^2 : 1 ml	10.0 ml	50 ℃, 72 h	Clear
	30.0 cm^2	Sesame oil	3 cm^2 : 1 ml	10.0 ml	50 ℃, 72 h	Clear

8.2 Test method

Use the rabbits with healthy intact skin. Fur is generally clipped on the back of the rabbits 16 h before testing, 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 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 as shown in Figure 1. And then wrap the application site with a bandage (semi-occlusive) for 4 h. At the end of the contact time, remove the dressings.



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

Figure1 Location of skin application sites

8.3 Observation of animal

Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 2 for each application site at each time interval. Record the appearance of each application site at 1 h, 24 h, 48 h and 72 h following removal of the patches.

Table 2 Classification 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 oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-defined by definite raising)	2
Moderate oedema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	**8**

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

8.4 Result calculation

Use only 24 h, 48 h and 72 h observations for calculation.

After the 72 h grading, all erythema grades plus oedema grades 24 h, 48 h and 72 h are totalled separately for each test sample and blank for each animal. The primary irritation score for an animal is calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).

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

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.

9.0 Evaluation criteria

The primary irritation index is characterized by number (score) and description (response category) given in Table 3.

Table 3 Primary irritation index categories in a rabbit

Mean score	Response category
0-0.4	Negligible
0.5-1.9	Slight
2.0-4.9	Moderate
5-8	Severe

10.0 Results of the test

According to what observed, the response of skin on testing side did not exceed that on the control side. See Table 4 .

Table 4 Dermal observations

Extraction solvent	Rabbit No.	Group		Interval			
				1h	24h	48h	72h
0.9% sodium chloride injection	J1501	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	J1502	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	J1503	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
Sesame oil	F1501	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	F1502	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	F1503	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0

The primary irritation indexes of the polar and non-polar test group were both calculated to be 0. Under the conditions of this study, the extract of the test article did not induce skin irritation.

11.0 Deviation statement

There was no deviation from the standard operating procedure which were judged to have any impact on the validity of the data.

12.0 Record

All the original data and records related to this test and copies of the final report are retained in the archives of Science Standard Medical Testing.

13.0 Confidentiality agreement

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

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TESTING
CNAS L10066

Test Report

Report Number: SSMT-R-2020-01188-03

Sample Name: Disposable medical surgical Mask

Study Title: Skin Sensitization Test - 0.9% Sodium Chloride Injection Extract

Standard: ISO 10993-10:2010

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

Weihai Dishang Medical Technology CO .,Ltd

Room 406-409, Block C, No.213 Torch Road, Torch High-tech Industrial Development Zone, Weihai, Shandong, China

Report No.: SSMT-R-2020-01188-03

Contents

Explanation

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.
6. This experiment was carried out in the sub-site and the address is: No. 68, Yaoluo Road, Wujin District, Changzhou City.

Report No.: SSMT-R-2020-01188-03

Conclusion

The extract of the test article was evaluated for its potential to induce skin sensitization in the Guinea Pig Maximization Test.

The test article were extracted with 0.9% sodium chloride injection. The test article extract was intradermally injected and applied topically for induction to ten guinea pigs. Five control animals were treated accordingly but with the solvent alone.

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

Study verification and signature

The study was carried out in accordance with the standard operating procedure. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (ISO/IEC17025:2017, IDT) and RB/T214-2017.

Date Received	2020-05-07
Technical Initiation Date	2020-05-18
Technical Completion Date	2020-06-11
Final Report Completion Date	2020-06-11

Edited by Molly 2020.06.11 Date

Checked by Suri 2020.06.11 Date

Approved by Daisy 2020.06.12 Date
Authorized signatory

Jiangsu Science Standard Medical Testing Co., Ltd.

1.0 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization using Guinea Pig Maximization Test.

2.0 Reference

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

Biological evaluation of medical devices-Part 12:Sample preparation and reference materials(ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

3.0 Test and control articles

3.1 Test article (The information about the test article was supplied by the sponsor wherever applicable.)

Test article name: Disposable medical surgical Mask

Sterilization state: Unsterilized

Model: DS01-WHITE/DS02-BLUE

Size: N/S

Lot/ Batch#: N/S

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

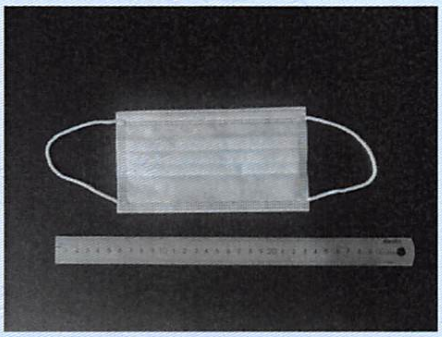
Solubility: N/S

Test Article Material: N/S

Packing Material: N/S

Storage Condition: Room Temperature

Sample photograph:



3.2 Control Article

Name: 0.9% Sodium chloride injection (SC)

Manufacturer: Chenxin Pharmaceutical Co., Ltd.

Size: 250 ml

Physical State: Liquid

Color: Colourless

Lot/ Batch#: 1906112830

Storage Condition: Room Temperature

4.0 Identification of test system

Species: Hartley Guinea Pig (Cavia Porcellus)

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

Sex: Males

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

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

Animal identification: Stain with picric acid

The quarantine period: 5 days

5.0 Animal Care and Maintenance

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

Bedding: NA

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

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

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

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

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy, previously unused animals were selected

Veterinarian: Vet takes care of the whole course

Ethics: Test methods of operation were reviewed and approved by the Commission on Science Standard animal ethics

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

6.0 Justification of the test system

6.1 The guinea pig is believed to be the most sensitive animal model for this type of study .The susceptibility of the guinea pig to a known sensitizing agent, dinitrochlorobenzene (DNCB) has been substantiated at SSMT. The skin sensitized positive control test is conducted every six months. The last allergenic rate is 100%. The data was from the report SSMT-R-2020-00198-01 (Date: 2020-04-05) .

6.2 The test article was extracted and administered in vivo through a medium compatible with the test system, which is considered as the best route of administration.

7.0 Instruments and reagents

7.1 Instruments

Digital oscillation incubator (SSMT-300)

Steel straight ruler (SSMT-210)

Electronic balance (SSMT-075)

Electronic balance (SSMT-147)

Clean bench (SSMT-187)

7.2 Reagents

Sodium dodecyl sulfate (SDS)

Freund's Adjuvant, Complete liquid

8.0 Experiment design and dose

8.1 Sample preparation

The test article was extracted as Table 1. Extract was checked and used immediately after extraction without the process of filtering, centrifugation, dilution, etc. The pH of the extract was not adjusted prior to testing. The preparation process was aseptic. The control article was prepared under the same condition.

Table 1 Sample Preparation

Aseptic Sampling			Aseptic Agitation Extraction In Inert Container				Final Extract
Sampling Manner	Test phase	Actually Sampling	Extraction solvent	Extraction ratio	Solvent volume	Condition	Clear or Not
Random sampling	Intradermal induction phase I	30.0 cm^2	0.9% sodium chloride injection	3 cm^2 : 1 ml	10.0 ml	50 ℃, 72 h	Clear
	Topical induction phase II	30.0 cm^2			10.0 ml	50 ℃, 72 h	Clear
	Challenge phase	30.0 cm^2			10.0 ml	50 ℃, 72 h	Clear

8.2 Test method

8.2.1 Intradermal induction phase I

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

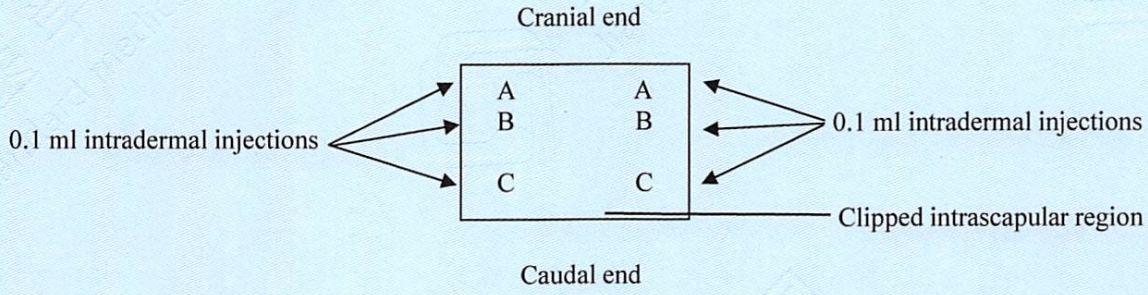


Figure 1 Location of intradermal injection sites

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

Site B: The test sample (undiluted extract); inject the control animals with the control articles 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 (50%); inject the control animals with an emulsion of the blank liquid with adjuvant.

8.2.2 Topical induction phase II

At 6 d after completion of the intradermal induction phase, administer the test sample by topical application to the intrascapular region of each animal, using a patch of area approximately 8 cm^2 (absorbent gauze) soaked with 0.5 ml extract, so as to cover the intradermal injection sites. Use the concentration selected in the intradermal induction phase for site B. If the maximum concentration that can be achieved in Intradermal induction phase I did not produce irritation, animals were pretreated with 10% sodium dodecyl sulfate 24 hours before the topical induction application. Secure the patches with an occlusive dressing. Remove the dressings and patches after 48 h.

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

8.2.3 Challenge phase

At 13 d after completion of the topical induction phase, challenge all test and control animals with the test sample. Administer the test sample and a blank by topical application to left and right abdomen of animals respectively, using absorbent gauze (about 8 cm^2) soaked with 0.5ml extracts or solvent control. Secure with an occlusive dressing. Remove the dressings and patches after 24 h.

8.3 Observation of animal

Observe the appearance of the challenge skin sites of the test and control animals 24 h and 48 h after removal of the dressings. 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 Table 2 for each challenge site and at each time interval.

Table 2 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

Report No.: SSMT-R-2020-01188-03

9.0 Evaluation criteria

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

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

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

10.0 Results of the test

The skin response of guinea pigs is shown in Table 3.

Table 3 Guinea pig Sensitization Dermal Reactions

Group	Animal Number	Excitation patch removed 24 h	Excitation patch removed 48 h	Positive rate after challenge phase	Weight range before injection (g)	Weight range after experiment (g)	Abnormal appearance except dermal reactions
Control	J1001	0	0	0%	316.4-379.2	476.5-531.6	None
	J1002	0	0				None
	J1003	0	0				None
	J1004	0	0				None
	J1005	0	0				None
Test	J2001	0	0	0%	309.2-365.2	459.3-539.2	None
	J2002	0	0				None
	J2003	0	0				None
	J2004	0	0				None
	J2005	0	0				None
	J2006	0	0				None
	J2007	0	0				None
	J2008	0	0				None
	J2009	0	0				None
	J2010	0	0				None

Under the conditions of this study, the test article did not show significant evidence of causing skin sensitization in the guinea pig. The skin sensitization rate was determined with 0%.

11.0 Deviation statement

There was no deviation from the standard operating procedure which were judged to have any impact on the validity of the data.

12.0 Record

All the original data and records related to this test and copies of the final report are retained in the archives of Science Standard Medical Testing.

13.0 Confidentiality agreement

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

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