TEST REPORT

Test Report No. 70.405.20.4933.01
Dated 2020-04-13

ORIGINAL

Order No.	:	-
Style No.	:	25 gsm
Season	:	-
	:	
Buyer	:	-
Country Of Origin	:	China
Goods Export To	:	-
Care Label Provided	:	-
Receipt Date Of Sample	:	Received On 2020-03-12
Date Of Testing	:	From 2020-03-12 To 2020-04-13
Sample Submitted	:	The Sample(s) Was (Were) Submitted By Applicant and Identified.
Test Result	:	Refer To Next Page.

TÜV SÜD Certification and Testing (China) Co., Ltd. Shanghai Branch
Testing Center

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TEST REPORT

Test Report No. 70.405.20.4933.01
Dated 2020-04-13

ORIGINAL

Description Of The Test Subject

Sample	Description	Photo
001	PP Meltblown nonwoven fabric in white for mask	

Test Results

1.Bacterial Filtration Efficiency (BFE) Test

1. Purpose
For evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask material.

2. Sample description was given by the client
Meltblown cloth

3. References
ASTM F2101-2019

4. Apparatus and materials
4.1 Staphylococcus aureus ATCC 6538
4.2 Peptone water
4.3 Tryptic Soy Broth (TSB)
4.4 Tryptic Soy Agar (TSA)
4.5 Bacterial filtration efficiency test apparatus
4.6 Six-stage viable particle Anderson sampler
4.7 Flow meters

5. Test specimen
5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21 ± 5) ° C and (85 ± 5) % relative humidity.

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6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the culture in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specimen to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediately begin sampling the aerosol using the Anderson sampler.
6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen in contact with the challenge.
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (35 ± 2) ℃ for (48 ± 4) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the counts from each of the six plates for the test specimens and positive controls, as specified by the manufacturer of Anderson sampler. The filtration efficiency percentages are calculated as follows:
BFE (%) =(C-T)/C × 100
where:
C = average plate count total for positive controls
T = plate count total for sample

8. Test results

Test Items	Test Results 001		Test Methods
Bacterial Filtration Efficiency (BFE) (%) Staphylococcus aureus ATCC 6538	1	99.5	ASTM F2101-2019
	2	99.5	
	3	99.6	
	4	99.7	
	5	99.6	

Note: 1. Control average: 2451 CFU.
2. Mean particle size: 3.0 μm.
3. Testing side: random sampling in both sides.
4. Testing area: 39.5 cm^2.

-End of The Test Report-

Sample name: Nonwoven fabric
Batch No./Date: 20200320

Above sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

SGS job No.: GZCPCH200301146
Date of receipt: 2020-03-25
Testing period: 2020-03-25~2020-04-14

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
Please refer to next page(s).

TEST METHOD(S):
Please refer to next page(s).

TEST RESULT(S):
Please refer to next page(s).

This test report has been drafted in English and maybe translated into other languages, The English version shall prevail.

Signed for and on behalf of SGS

.....
Authorized Signature
Denny Li

TEST RESULT:
Test request: Dermal Irritation Test*

Test method: with reference to ISO 10993-10:2010, Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization.

Test environment: Rabbit room of conventional condition. The license number of using laboratory animals is No. SYXK(粤) 2018-0086; Room temperature 21~23℃,Relative humidity 55~65%.

Test animal: New Zealand white albino rabbits, weighing between 2.1kg and 2.3kg at the start of the test,were used. They were supplied by Guangdong Medical Laboratory Animal Center (Sanshui Base). The production license number of laboratory animals is No. SCXK(粤)2019-0035. The animal certificate number is No. 44411600006527.
No. of animals/sex: 3/♀:♂=2:1

Preparation of Sample: The sample was cut to 2.5 cm×2.5 cm /piece and moistened with deionized water as test substance.

Observation period: 1±0.1h, 24±2h, 48±2h and 72±2h hours following removal of the test substance, use only 24±2h, 48±2h and 72±2h observations for calculations.

Test procedures: (1) Preparation of test animals. Selected three healthy young adult New Zealand white albino rabbits. Fur was shaved 24h before the test (approximately 10cm×15cm). (2) Procedures for testing. The test substance was applied to the test sides as shown in Figure 1 of test method with a gauze patch respectively Applied the control patch of gauze (was moistened with deionized water) on the control site indicated in Figure 1 of test method. And then the application sites were wrapped with a non-irritation tape and bandage for 4 hours. At the end of the contact time, removed the dressings and marked the sites, removed and wiped the residual test substance using warm water. Examined for signs of erythema and edema, recorded the dermal reactions at each observation period according to "Table 1" and "Table 2" in test method.

Result(s):
The Primary Irritation Index(PII) of the test substance is 0.

The scores of the test substance

Observation period	(1±0.1)h								(24±2) h							
Skin reaction	Erythema-eschar				Edema				Erythema-eschar				Edema			
Skin application site / Rabbit Number	Test Site		Control Site		Test Site		Control Site		Test Site		Control Site		Test Site		Control Site	
	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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Observation period	(48±2) h								(72±2) h							
Skin reaction	Erythema-eschar				Edema				Erythema-eschar				Edema			
Skin application site / Rabbit Number	Test Site		Control Site		Test Site		Control Site		Test Site		Control Site		Test Site		Control Site	
	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Note: 1. L= Left, R = Right
2. *Test was carried out by external laboratory assessed as competent.

Reference information:

ISO 10993-10:2010 Table2- 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

SAMPLE DESCRIPTION: Sheet sample

Photo Appendix

*** End of Report***

Sample name: Nonwoven fabric
Batch No./Date: 20200320

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SGS job No.: GZCPCH200301146
Date of receipt: 2020-03-25
Testing period: 2020-03-25~2020-04-16

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
Please refer to next page(s).

TEST METHOD(S):
Please refer to next page(s).

TEST RESULT(S):
Please refer to next page(s).

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Signed for and on behalf of SGS

.....
Authorized Signature
Denny Li

TEST RESULT:
Test request: Cytotoxicity*
Test method: With reference to ISO 10993-5: 2009<Biological evaluation of medical devices-Part5: Tests for in vitro cytotoxicity>

1. Summary:

According to the ISO 10993-5: 2009 *Biological evaluation of medical devices-Part5: Tests for in vitro cytotoxicity*, take advantage of Annex C: MTT cytotoxicity test to determination of cytotoxicity of test article(TA) extracts.

2. Materials:

2.1 Cell lines: L-929 cell (NCTC clone 929). Source: Kunming Cell Bank. Generation: 32.
2.2 Culture medium: DMEM with 10% fetal bovine serum (FBS, from Gibco, Lot: 2045512CP).
2.3 Test condition: Incubate at 37±1℃ and >90% humidity in air with 5% CO_2 (volume fraction).
2.4 TA storage conditions: Room temperature.
2.5 Test extract preparation: According to *ISO 10993-12: Biological evaluation of medical devices-Part12: Sample preparation and reference materials*, the TA was extracted following the extraction rate 0.1 g/mL with culture medium. The negative control and positive control materials were extracted following the extraction rate 0.2 g/mL with culture medium.
2.6 Blank control (BC): DMEM with 10% fetal bovine serum
2.7 Negative control (NC): Polyethylene, high density Granules, CAS#9002-88-4
2.8 Positive control (PC): Zinc Diethyldithiocarbamate, CAS#14324-55-1
2.9 Condition of extracts: Incubate at 37±1℃ and at 200 rpm/minute for 24±2 hours.

3. Methods:

3.1 Experimental Procedure:
3.1.1 All test sample and controls used the same pre-treatment and operating procedure. Took 0.6814 g of sample, added 6.81 mL DMEM culture solution containing 10% fetal bovine serum into glass bottle. Kept at 37±1℃ and 200 rpm / minute for 24±2 hours as original extraction（100%）.
3.1.2 The L-929 cells were cultured routinely in sterile flask. After the cells re-suspended in culture medium and the cell suspension was adjusted and seeded at a density of 1×10⁴ cells/100 μL/well into 96-well tissue culture microtitre plate and the PBS was dispensed into peripheral wells follow the rule

of 100 µL/ well. Subsequently, the plates were put in incubator for 24±2 hours to form a half-confluent monolayer.

3.1.3 The original extraction (100%) was distributed and diluted into 75%, 50% and 25%. Meanwhile, six replicates should be used for TA and controls. The plate was taken out from incubator and the medium was discarded. Then added 100 µL of treatment medium containing the appropriate concentration of TA extract (100%, 75%, 50% and 25%), the NC, PC and BC (medium-only). The plate was incubated for 24 ±0.5 hours.

3.1.4 Carefully removed the culture medium from the plates. 50 µL of MTT solution (1 mg/mL) was added into each well, and incubated for 2 hours±20 minutes at 37℃. The MTT solution was then removed, and 100 µL of isopropanol was added to each well. The absorbance was measured at 570 nm after swaying for 10-15 minutes in the dark.

3.2 Evaluation criteria:

$$\text{Viability}(\%) = \frac{OD_{570} \text{ of TA/PC/NC}}{OD_{570} \text{ of BC}} * 100$$

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

The 50% extract of the TA should have at least the same or higher viability than the 100% extract; otherwise the test should be repeated.

3.3 Test quality check:

A test meets the acceptance criteria if the mean OD_{570} of blanks is ≥0.2.

A test meets acceptance criteria if the left and the right mean of the blanks do not differ by more than 15% from the mean of all blanks.

4. Results:

The results of show as table 1.

Table 1. The results of the test (Mean±SD)

Group	OD	Viability (%)
Blank control	1.0402±0.0643	100.00±6.45
Negative control	0.9742±0.0757	93.38±7.59
25%	1.0114±0.0850	97.12±8.52
50%	0.9422±0.0703	90.18±7.05
75%	0.8719±0.0437	83.12±4.38
100%	0.8141±0.0408	77.33±4.09
Positive control	0.2270±0.0271	18.46±2.72

Remark: *Test was carried out by external laboratory assessed as competent.

SAMPLE DESCRIPTION: Sheet sample

Photo Appendix

*** End of Report***