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CNAS L0599

Test Report SL52025244426101TX Date: July 20, 2020 Page 1 of 6

SHANDONG SHENGQUAN NEW MATERIALS CO., LTD.  
INDUSTRY DEVELOPMENT ZONES, DIAOZHEN TOWN, ZHANGQIU, SHANDONG

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

Sample Description : (A) Nowoven (Biomass Graphene Composite Meltblown Nowoven)

Sample Color : (A) black

Lot No./Batch No. : Not provided

Proposed Care Instruction : -

Test Performed : Selected test(s) as requested by applicant

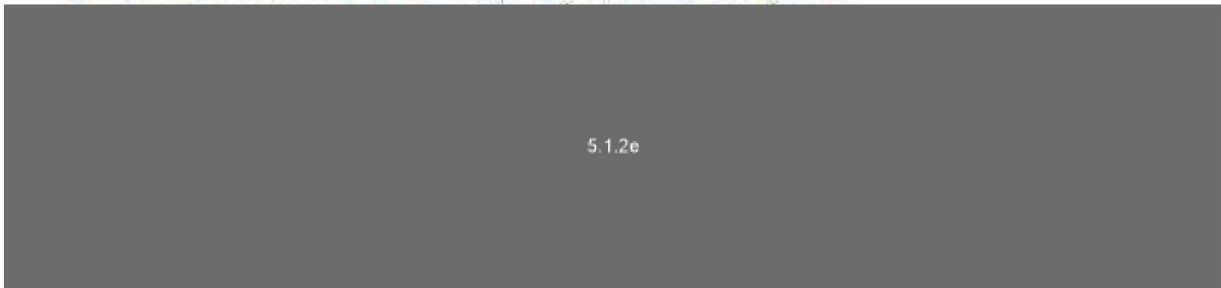
Sample Receiving Date : Apr 08, 2020

Testing Period : Apr 09, 2020 - Jul 20, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

<p>Conclusion Biocompatibility</p>	<p>(A) <b>Vitro cytotoxicity:</b> non cytotoxic effect <b>Animal Skin Irritant Test:</b> <b>normal saline:</b> negligible irritant <b>cotton seed oil:</b> negligible irritant <b>Skin Sensitization test:</b> <b>normal saline:</b> no evidence of causing delayed dermal contact sensitization <b>cotton seed oil:</b> no evidence of causing delayed dermal contact sensitization</p>
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Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center



5.1.2e



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Test Result

**Tests for in vitro cytotoxicity (test on extracts)**  
(ISO 10993-5:2009)

**TEST METHOD(S):**

ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity

Test Article: The sample preparation was in accordance with ISO 10993-12:2002. Extration condition is 24h at 37 °C in culture medium. The volume of extract is determined by the standard surface area.

Cell lines: L-929 cells (mouse fibroblast)

Medium: 1640 medium (Gibco) with 10% FBS

Chromogenic reagent: MTT

Negative control: Polyethylene

Positive control: Phenol diluted solution (5g/L)

General Procedure: The prepared cell suspension was seeded in 96-well culture plate, set blank control, negative control, the positive control and the test sample group, inoculated with 100µL of cell suspension per well. Set CO<sub>2</sub> incubator (5% CO<sub>2</sub>, the same below) 37 °C cultured for 24 h, discard the original culture medium. Adding fresh cell culture medium in blank control group, added extracts of the negative control in negative control group, added positive control solution or positive control extracts in the positive control group, added the extracts of the experimental material in the test sample. The test volume is 100µL per well, set CO<sub>2</sub> incubator cultured for 24h. Observed cell morphology under the microscope. Added 20µL 5g/L MTT solution, cultured 4h, discarded liquid, added 150µL DMSO and shaken 10min. Measure the absorbance at 570 nm and 630 nm and RGR was calculated, to determine the cytotoxic response.

**TEST RESULT(S):**

The cell viability is 82%, cell growth state in blank control, negative control and positive control is normal

Attached table: Test result

	Viability of the test sample/%
Parallel sample 1	83
Parallel sample 2	83
Parallel sample 3	81

**CONCLUSION:**

The sample is non cytotoxic effect.

According to the ISO 10993.5-2009, the result of cell viability ≥70% is considered non cytotoxic effect.



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### Animal Skin Irritant Test\*

(ISO 10993.10-2010)

#### Test animal

Three healthy conventional New Zealand White Rabbits, female, 2.0-3.0 kg each, supplied by Shanghai KeShuo Experiment Animal Co., LTD, Certificate No. SCXK(Hu)2017-0013. The animal feed were supplied by JiaShan chenchen food Co., LTD, license No. Zhe Feed Approval(2014)06017.

#### Test environment

Rabbit room of conventional condition. Certificate No. SYXK(Hu)2019-0033, room temperature 18-23℃, relative humidity 45-65%.

#### Sample preparation

The extract of the sample was performed in normal saline in 37℃ for 72h, the extraction ratio was 3.0 cm<sup>2</sup>/ml.

### Test Results

Tab.1

Rabbit Number	response	Observation time					
		24 h		48 h		72 h	
		Sample S	Contrast C	Sample S	Contrast C	Sample S	Contrast C
4419#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0
4420#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0
4421#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0

The Primary Irritation Score of the extract of the sample was 0.

Tab.2 Primary 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

### Conclusions

According to Primary irritation index categories in a rabbit, the extract of the test sample was found to be a negligible irritant to rabbits' skin.



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**Sample preparation**

The extract of the sample was performed in cotton seed oil in 37 °C for 72h, the extraction ratio was 3.0 cm<sup>2</sup>/ ml.

**Test Results**

Tab.1

Rabbit Number	response	Observation time					
		24 h		48 h		72 h	
		Sample S	Contrast C	Sample S	Contrast C	Sample S	Contrast C
4422#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0
4423#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0
4424#	Erythema	0	0	0	0	0	0
	Edema	0	0	0	0	0	0

The Primary Irritation Score of the extract of the sample was 0.

Tab.2 Primary 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

**Conclusions**

According to Primary irritation index categories in a rabbit, the extract of the test sample was found to be a negligible irritant to rabbits' skin



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### Skin Sensitisation test\* (ISO 10993-10:2010)

#### Test environment

Animal room of conventional condition. Certificate No. SYXK(Hu) 2019-0033, room temperature 20-22°C, relative humidity 45-65%.

#### Experimental animals

Guinea pigs, female, 300-500g, supplied by Shanghai KeShuo Experiment Animal Co., LTD, Certificate No. SCXK(Hu)2017-0013). The animal feed were supplied by Jiangsu Xietong Medical bio-engineering Co. LTD. License No: Su Feed Approval(2014) 01008.

#### Sample preparation

The extract of the sample was performed in normal saline in 37°C for 72h, the extraction ratio was 6.0 cm<sup>2</sup>/ ml.

#### Test results

Delayed hypersensitivity tests results of face mask

Group	Time(h)	Skin response				Sensitization rate %
		0	1	2	3	
Normal saline	24	5	0	0	0	0
	48	5	0	0	0	0
The extract of the test article	24	10	0	0	0	0
	48	10	0	0	0	0

#### Magnusson and Kligman scale Patch test reaction Grading scale

Patch test reaction	Scoring
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

#### Conclusions

Under the conditions of the study, the extract of the test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig



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**Sample preparation**

The extract of the sample was performed in cotton seed oil in 37 °C for 72h, the extraction ratio was 6.0 cm<sup>2</sup>/ ml.

**Test results**

Delayed hypersensitivity tests results of the extract of face mask

Group	Time(h)	Skin response				Sensitization rate %
		0	1	2	3	
Normal saline	24	5	0	0	0	0
	48	5	0	0	0	0
The extract of the test article	24	10	0	0	0	0
	48	10	0	0	0	0

**Magnusson and Kligman scale Patch test reaction Grading scale**

Patch test reaction	Scoring
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

**Conclusions**

Under the conditions of the study, the extract of the test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

**Remark:**

\* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment) L1009.

**Sample Photo**

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\*\*\*



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