

SGS



中国认可
国际互认
检测
TESTING
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).

Conclusion	(A)
Biocompatibility	<p>Vitro cytotoxicity: cytotoxic effect Animal Skin Irritant Test normal saline: negligible irritant cotton seed oil: negligible irritant Skin Sensitization test: normal saline: no evidence of causing delayed dermal contact sensitization cotton seed oil: no evidence of causing delayed dermal contact sensitization</p>

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

5.1.2e

5.1.2e

5.1.2e

(Authorized Signatory)

5.1.2e

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: 5.1.2e

or email: sgs@sgs.com

3rd Building, No.888, Yishan Road, Xuhui District Shanghai, China 200233
中国·上海·徐汇区宜山路888号3号楼 邮编: 200233

5.1.2e

www.sgs.com.cn
e 5.1.2e@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52025244426101TX

Date: July 20, 2020

Page 2 of 6

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℃ 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 CO₂ incubator (5% CO₂, the same below) 37℃ 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 CO₂ 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.

5.1.2e

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone

or email: sgs@sgs.com
3rd Building, No.888, Yishan Road, Xuhui District Shanghai, China 200233
中国·上海·徐汇区宜山路888号3号楼 邮编: 200233

5.1.2e

5.1.2e
www.sgsgroup.com.cn
e 5.1.2e@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52025244426101TX

Date: July 20, 2020

Page 3 of 6

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 cm²/ 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.

5.1.2e

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone:

or email: sgs@sgs.com

3rd Building, No.888, Yishan Road, Xuhui District Shanghai, China 200233
中国·上海·徐汇区宜山路888号3号楼 邮编: 200233

5.1.2e

www.sgs.com.cn
e 5.1.2e@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52025244426101TX

Date: July 20, 2020

Page 4 of 6

Sample preparation

The extract of the sample was performed in cotton seed oil in 37°C for 72h, the extraction ratio was 3.0 cm²/ 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

5.1.2e

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated or results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone:

or email: sgs@sgs.com

3rd Building, No.888, Yishan Road, Xuhui District Shanghai, China 200233
中国·上海·徐汇区宜山路888号3号楼 邮编: 200233

5.1.2e

www.sgs.com.cn
e 5.1.2e@sgs.com

Member of the SGS Group (SGS SA)



Test Report

SL52025244426101TX

Date: July 20, 2020

Page 5 of 6

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

Test environment

Animal room of conventional condition. Certificate No. SYXK(Hu) 2019-0033, room temperature 20-22℃, 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℃ for 72h, the extraction ratio was 6.0 cm²/ 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

5.1.2e

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone:

or email: china@sgs.com

3rd Building, No.888, Yishan Road, Xuhui District Shanghai, China 200233
中国·上海·徐汇区宜山路888号3号楼 邮编: 200233

5.1.2e

www.sgs.com
e china@sgs.com

5.1.2e

Member of the SGS Group (SGS SA)

Sample preparation

The extract of the sample was performed in cotton seed oil in 37°C for 72h, the extraction ratio was 6.0 cm²/ 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

5.1.2e

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone

or email: sgs@sgs.com
 3rd Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233
 中国·上海·徐汇区宜山路889号3号楼 邮编: 200233

5.1.2e

www.sgs.com.cn
 e 5.1.2e@sgs.com

5.1.2e

Member of the SGS Group (SGS SA)