| SGS | | | C-MRA | NAS | 中国认可 国际互认 检测 TESTING CNAS L0599 |
|---------------------------|-------|--|-------------------|---------------|---|
| Test Report | SL | 52025244426101TX | Date:July | 20,2020 | Page 1 of 6 |
| INDUSTRY DEVELOPME | NT 2 | EW MATERIALS CO., LTD. ZONES, DIAOZHEN TOWN | , ZHANGQIU, SHA | | |
| | də/ w | | | | |
| Sample Description | 3.4 | (A) Nowoven (Biomass Gr | apriene Composite | Wellplown Now | overn |
| Sample Color | | (A) black | | | |
| Lot No./Batch No. | 12 | Not provided | | | |
| Proposed Care Instruction | : | | | | |
| Test Performed | | Selected test(s) as reques | ted by applicant | | |
| Sample Receiving Date | 2 | Apr 08, 2020 | | | |
| Testing Period | 10.00 | Apr 09, 2020 - Jul 20, 2020 | D | | |
| Test Result(s) | 81 | Unless otherwise stated th sample(s) tested, for furthe | | | |

| Conclusion | (A) |
|------------------|---|
| Biocompatibility | Vitro cytotoxicity:non 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 |

Signed for and on behalf of

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

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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

Medium: 1640 medium (Gibco), with 10%

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 °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 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.



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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°C, relative humidity 45-65%.

Sample preparation

The extract of the sample was performed in normal saline in 37 °C for 72h, the extraction ratio was 3.0 cm²/ml.

Test Results

| а | | |
|---|--|--|
| | | |

| | | Observation time | | | | | | |
|-----------------|----------|------------------|----------|------------|----------|------------|---|--|
| Rabbit response | | 24 h | | 48 h | | 72 h | | |
| Number | Sample S | Contrast C | Sample S | Contrast C | Sample S | Contrast C | | |
| 4419# - | Erythema | 0 | 0 | 0 | 0 | 0 | 0 | |
| 4419# - | Edema | 0 | 0 | 0 | 0 | 0 | 0 | |
| 4420# - | Erythema | 0 | 0 | 0 | 0 | 0 | 0 | |
| 4420# - | Edema | 0 | 0 | 0 | 0 | 0 | 0 | |
| 4421# - | Erythema | 0 | 0 | 0 | 0 | 0 | 0 | |
| 4421# - | Edema | 0 | 0 | 0 | 0 | 0 | 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 cm²/ ml.

Test Results Tab.1

| - | | 12 | | Observ | ation time | | |
|------------------|----------|-----------------------------|------------|------------|---------------------------------|----------|------------|
| Rabbit Number | 24 h | | 48 h | | 72 h | | |
| Number | 92 | Sample S | Contrast C | Sample S | Contrast C | Sample S | Contrast C |
| 4422# - | Erythema | 0 | 0 | 0 | 0 | 0 | 0 |
| 4422# - | Edema | 0 | 0 | 0 | 0 | 0 | 0 |
| 4423# - | Erythema | 0 | 0 | 0 | 0 | 0 | 0 |
| 4423# - | Edema | 0 | 0 | 0 | 0 | 0 | 0 |
| 4424# - | Erythema | 0 | 0 | 0 | 0 | 0 | 0 |
| 4424# - | Edema | 0 | 0 | 0 | 0 | 0 | 0 |
| | The I | Primary Irritati Tab.2 P | | | the sample w gories in a rat | | |
| Mea | in score | | 12 | Response | category | | 26 |
| 0~0 |).4 | | | Negligible | 6.05 | | 1 |
| 0.5- | -1.9 | | | Slight | | | |
| 2~4 | 1.9 | | | Moderate | | | |
| 5~8 | 3 | | | 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 Xletong 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 cm²/ml.

Test results

Delayed hypersensitivity tests results of face mask

| Group | Time(h) - | | Sensitization rate % | | | |
|--------------------|-----------|----|----------------------|---|---|---|
| Group | nine(n) | 0 | Ť, | 2 | 3 | |
| | 24 | 5 | 0 | 0 | 0 | 0 |
| Normal saline — | 48 | 5 | 0 | 0 | 0 | 0 |
| The extract of the | 24 | 10 | 0 | 0 | 0 | 0 |
| test article | 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 cm²/ ml.

Test results

Delayed hypersensitivity tests results of the extract of face mask

| Group Time | Time (b) | Skin response | | | | O |
|--------------------|----------|---------------|---|---|---|---|
| | time(n) | 0 | 1 | 2 | 3 | |
| Normal saline 48 | 24 | 5 | 0 | 0 | 0 | 0 |
| | 48 | 5 | 0 | 0 | 0 | 0 |
| The extract of the | 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.



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

