

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

Sample Description : (A) Disposable medical face mask
Style No. : JM01
Composition : (A) 33.3% non-woven fabric + 33.3% melt-blown fabric + 33.4% non-woven fabric
Sample Color : (A) Blue
Lot No./Batch No. : 2020013

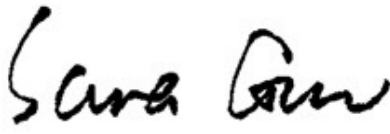
Proposed Care Instruction : -

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

Sample Receiving Date : May 14, 2020
Testing Period : May 14, 2020 - Aug 17, 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).

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



Sara Guo (Account Executive)



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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.6 Biocompatibility

(ISO 10993-1)

Tests for in vitro cytotoxicity (test on extracts)*

(ISO 10993-5:2009)

Cell line

Mouse fibroblast cells L929 was purchased from cell bank of Chinese Academy of Sciences, Shanghai.

Cell culture medium

1640 medium, supplemented with L-glutamine and 10% FBS.

Sample preparation

The test article was sterilized at 121 °C for 30 min and was extracted with 1640 Medium in ratio of 3 cm²/mL in 37 °C for 24h. Positive control: Polyurethane film containing 0.1% zinc diethyl-dithiocarbamate (ZDEC).

Test procedures

L929 cells were cultured in RPMI 1640 medium with 10% FBS and Penicillin-Streptomycin, and placed in cells incubator of 37 °C and 5.0% CO₂.

L929 cells were seeded in 96-well plates and each well was added 100 µl cell solution in a density of 1×10⁵/ml. Cells were treated with the extract of the test sample and 6 replicate wells were used.

After 24h treatment, 50 µl MTT solution were add to each wells. After incubation, washing and Isopropanol extraction, the absorbance of each well was detected at 570 nm with a spectrophotometer and cell viability were calculated.

Test results

Cytotoxicity tests results of face mask

| Group | Cell viability |
|------------------|----------------|
| Solution control | 100% |
| Test article | 104.23% |
| Positive control | 1.03% |

Conclusions

Under the conditions of this study, the negative controls and the positive controls in the test performed as anticipated, the cytotoxicity of the sample was grade 0, which is non-cytotoxic

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.



Animal Skin Irritant Test*

(ISO 10993.10-2010)

Test animal

Four 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 Huzhou Eastern Hope Animal Nutrition Food Co., LTD, license No. Zhe Feed Approval(2019)05022.

Test environment

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

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 |
| 5535# | Erythema | 0 | 0 | 0 | 0 | 0 | 0 |
| | Edema | 0 | 0 | 0 | 0 | 0 | 0 |
| 5536# | Erythema | 0 | 0 | 0 | 0 | 0 | 0 |
| | Edema | 0 | 0 | 0 | 0 | 0 | 0 |
| 5537# | Erythema | 0 | 0 | 0 | 0 | 0 | 0 |
| | Edema | 0 | 0 | 0 | 0 | 0 | 0 |

The Primary Irritation Score 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 sample was found to be a negligible irritant to rabbits' skin

Remark:

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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

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 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 test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig

Remark:

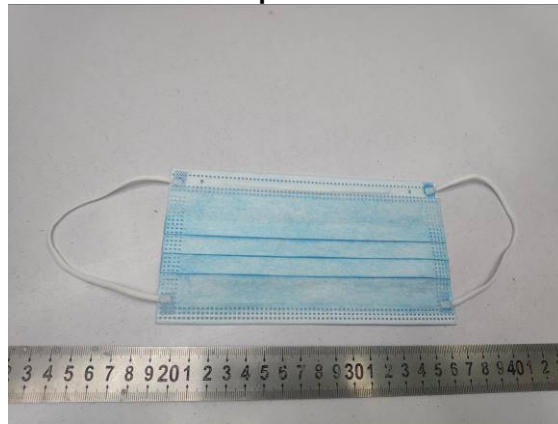
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Sample Photo



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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