

Test Report

No. TAOHG2004304401

Date: 30 Sep 2020

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BLUE SAIL MEDICAL CO.,LTD

NO.21 QINGTIAN ROAD,QILU CHEMICAL INDUSTRIAL PARK,ZIBO,SHANDONG,CHINA 255414

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE NITRILE GLOVES

SGS Job No. : QDHL2009010090CW - QD
 Date of Sample Received : 24 Sep 2020
 Testing Period : 24 Sep 2020 - 30 Sep 2020
 Test Requested : Selected test(s) as requested by client.
 Test Method : Please refer to next page(s).
 Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Council of Europe Resolution AP (2004) 4 -Overall migration	PASS
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 -Sensorial examination odour and taste test	PASS
Council of Europe Resolution AP (2004) 4 -Specific migration of primary aromatic amine	PASS
Council of Europe Resolution AP (2004) 4 -Specific migration of nitrosamine and nitrosatable substances	PASS

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



Wang Bo, Claire
 Approved Signatory

scan to see the report



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SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
 t (86-532) 68999888 f (86-532) 80991955

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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TAO20-043044.001	Blue rubber glove	Nitrile rubber

Remarks :

- (1) mg/dm² = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C= degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected (< MDL)

Council of Europe Resolution AP (2004) 4 -Overall migration

Test Method : With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of condition and EN 1186-1:2002 for selection of test methods;
EN 1186-9: 2002 aqueous food simulants by article filling method;
EN 1186-2: 2002 olive oil by total immersion method;

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 001 Overall Migration</u>	<u>Conclusion</u>
3% Acetic acid (W/V) aqueous solution	2.0hr(s)	70°C	10mg/dm ²	5.3mg/dm ²	PASS
10% Ethanol (V/V) aqueous solution	2.0hr(s)	70°C	10mg/dm ²	5.8mg/dm ²	PASS
Rectified olive oil	2.0hr(s)	70°C	10mg/dm ²	6.4mg/dm ²	PASS

Notes :

- (1) Analytical tolerance of aqueous simulants is 2 mg/dm² or 12 mg/kg.
- (2) Analytical tolerance of fatty food simulants is 3 mg/dm² or 20mg/kg.
- (3) Test condition & simulant were specified by client.
- (4) Report the first migration result.
- (5)The test of rectified olive oil simulant was subcontracted to SGS Shanghai chemical lab.

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 -Sensorial examination odour and taste test



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Test Method : With reference to DIN 10955: 2004
 Test media: Distilled water
 No. of panelist: 6

<u>Test Item(s)</u>	<u>Limit</u>	<u>001</u>
Test time (hr)	-	2
Temperature (°C)	-	40
Sensorial examination odour (Point scale)	2.5	0.0
Sensorial examination taste (Point scale)	2.5	0.0
Conclusion		PASS

Notes :

- Intensity scale (rounded at 0.5):
- 0 – no perceptible difference
 - 1 – just perceptible difference
 - 2 – slight difference
 - 3 – marked difference
 - 4 – strong difference

Council of Europe Resolution AP (2004) 4 -Specific migration of primary aromatic amine

Test Method : With reference to EN 13130-1: 2004, analysis was performed by UV-Vis.

Sample 001

Simulant Used : 3% Acetic acid (W/V) aqueous solution
 Test Condition : 40 °C 2.0 hr(s)

<u>Test Item(s)</u>	<u>Max. Permissible Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times	-	-	-	First
Area/volume	-	dm ² /kg	-	6.0
Specific migration of primary aromatic amine	0.01	mg/kg	0.01	ND
Conclusion				PASS

Notes :

- (1) Test condition & simulant were specified by client.
- (2) The test was subcontracted to SGS Shanghai chemical lab.

Council of Europe Resolution AP (2004) 4 -Specific migration of nitrosamine and nitrosatable substances

Test Method : With reference to EN 13130-1: 2004, analysis was performed by GC-MS.



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Sample 001

Simulant Used : 3% Acetic acid (W/V) aqueous solution

Test Condition : 40 °C 2.0 hr(s)

<u>Test Item(s)</u>	<u>Max. Permissible Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times	-	-	-	First
Area/volume	-	dm ² /kg	-	6.0
Specific migration of Nitrosamines	0.01	mg/kg	0.01	ND
Specific migration of Nitrosatable substances	0.1	mg/kg	0.1	ND
Conclusion				PASS

Notes :

- (1) Nitrosamines tested: N-nitrosodimethylamine (NDMA), N-nitrosodiethylamine (NDEA), N-nitrosodipropylamine (NDPA), N-nitrosodibutylamine (NDBA), N-nitrosopiperidine (NPIP), N-nitrosopyrrolidine (NPYR), N-nitrosomorpholine (NMOR), N-nitrosodibenzylamine (NDBzA), N-nitroso-N-methyl-N-phenylamine (NMPPhA), N-nitroso-N-ethyl-N-phenylamine (NEPhA), N-nitrosodiisononylamine (NDiNA) and N-Nitrosodiisobutylamine (NDiBA)
- (2) Test condition & simulant were specified by client.
- (3) The test was subcontracted to SGS Shanghai chemical lab.

Sample photo:



SGS authenticate the photo on original report only



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