

Test Report

No. TAOHG2106752601

Date: 29 Nov 2021

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HAINAN FOSUN MEDICAL TRADE LIMITED COMPANY

ROOM 203-1,205-10,207-2, INTERNATIONAL BUSINESS CENTER, CROSS-BORDER E-COMMERCE INDUSTRIAL PARK, HAIKOU COMPREHENSIVE BONDED ZONE, HAIKOU, HAINAN

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

SGS Job No. : QDHL2111513207CW - QD
Date of Sample Received : 17 Nov 2021
Testing Period : 17 Nov 2021 - 29 Nov 2021
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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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TAO21-067526.001	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	0.5hr(s)	40°C	10mg/dm ²	6.4mg/dm ²	PASS
10% Ethanol (V/V) aqueous solution	0.5hr(s)	40°C	10mg/dm ²	3.6mg/dm ²	PASS
Rectified olive oil*	0.5hr(s)	40°C	10mg/dm ²	<3.0mg/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 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)	-	0.5
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 0.5 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.

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.

Sample 001



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

Test Condition : 40 °C 0.5 hr(s)

Test Item(s)	Max. Permissible Limit	Unit	MDL	Test result
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-nitrosodiisobutylamine (NDiBA) 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

*** End of Report ***



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