Test Report

No. SHAHG2117665801 Date: 24 Aug 2021 Page 1 of 4

ZHONGHONG PULIN MEDICAL PRODUCTS CO.,LTD

WEST PARK OF ECONOMIC DEVELOPMENT ZONE, LUANNAN COUNTY, TANGSHAN CITY, HEBEI PROVINCE

The following sample(s) was/were submitted and identified on behalf of the clients as : POWDER FREE NITRILE GLOVE,BLACK

SGS Job No. :	SHHL2108043865CW - SH
Item No. :	0812-2
Manufacturer :	ZHONGHONG PULIN MEDICAL PRODUCTS CO.,LTD
Date of Sample Received :	16 Aug 2021
Testing Period :	16 Aug 2021 - 24 Aug 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 (Shanghai) Co., Ltd.

scan to see the report

SHAHG2117665801

Danna Ji
Approved Signatory

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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	SHA21-176658.001	Black rubber gloves	Nitrile rubber

Remarks :

(1) mg/dm² = milligram per square decimeter
(2) mg/kg = milligram per kilogram
(3) ℃= 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 1186-2: 2002 olive oil by total immersion method;
EN 1186-9: 2002 aqueous food simulants by article filling method.

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 001 Overall Migration	Conclusion
3% Acetic acid (W/V) aqueous solution	2.0hr(s)	70℃	10mg/dm²	10.0mg/dm²	PASS
10% Ethanol (V/V) aqueous solution	2.0hr(s)	70℃	10mg/dm²	4.1mg/dm²	PASS
Rectified olive oil	2.0hr(s)	70℃	10mg/dm²	<3.0mg/dm²	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.

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

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

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Test Item(s)	Limit	*001*
Test media	-	DW
Test time (hr(s))	-	0.5
Temperature(℃)	-	40
Sensorial examination odour (Point scale)	2.5	0
Sensorial examination taste (Point scale)	2.5	0
Conclusion		**PASS**

Notes :

Scale evaluation:
0 – no perceptible difference
1 – just perceptible difference
2 – slight difference
3 – marked difference
4 – strong difference
DW= Distilled water

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 ℃ 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 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

检验检测专用章 Inspection & Testing Services

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Simulant Used : 3% Acetic acid (W/V) aqueous solution
Test Condition : 40 ℃ 0.5 hr(s)

Test Item(s)	Max. Permissible Limit	Unit	MDL	Test result
Migration times	-	-	-	First
Area/volume	-	dm²/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 (NMPhA), N-nitroso-N-ethyl-N-phenylamine (NEPhA), N-nitrosodiisononylamine (NDiNA) and N-Nitrosodiisobutylamine (NDiBA)

(2) Test condition & simulant were specified by client.

Sample photo:



SHA21-176658.001

SGS authenticate the photo on original report only

*** End of Report ***

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