

Test Report

No. TAOHG1802365501

Date: 07 Jun 2018

Page 1 of 6

BLUE SAIL MEDICAL CO.,LTD

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

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE VINYL GLOVE,CLEAR

SGS Job No. : QDHL1805012043OT - QD
Item No. : XS、S、M、L、XL
Date of Sample Received : 30 May 2018
Testing Period : 30 May 2018 - 07 Jun 2018
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
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments -Overall migration	PASS
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments -Specific migration of phthalates	PASS
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments -Specific migration of heavy metal	PASS
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments -Phthalates	PASS
Commission Implementing Regulation (EU) 321/2011 amending Regulation (EU) 10/2011 of 14 January 2011-Bisphenol A	PASS
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments -Residual vinyl chloride monomer	PASS

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



Wang Bo, Claire
Approved Signatory



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Test Report

No. TAOHG1802365501

Date: 07 Jun 2018

Page 2 of 6

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TAO18-023655.001	Translucent plastic glove	PVC

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)

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments -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; or EN 1186-9: 2002 aqueous food simulants by article filling 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>
10% Ethanol (V/V) Aqueous Solution	2.0hr(s)	70°C	10mg/dm ²	<3.0mg/dm ²	PASS
3% Acetic Acid (W/V) Aqueous Solution	2.0hr(s)	70°C	10mg/dm ²	<3.0mg/dm ²	PASS
20% Ethanol (V/V) Aqueous Solution	2.0hr(s)	70°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) The test data is obtained by considering the articles intended for repeated use as per described in Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex V. Report the 3rd extractive result.

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments - Specific migration of phthalates

Test Method : With reference to EN13130-1:2004; analysis was performed by GC-MS.



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Test Report

No. TAOHG1802365501

Date: 07 Jun 2018

Page 3 of 6

Sample 001

Simulant Used : 95% Ethanol (V/V) Aqueous Solution

Test Condition : 40°C 2.0hr(s)

<u>Test Item(s)</u>	<u>CAS NO.</u>	<u>Max. Permissible</u> <u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times		-	-	-	First
Area/volume		-	dm ² /kg	-	6.0
Benzylbutyl Phthalate(BBP)	85-68-7	30	mg/kg	0.05	ND
Dibutyl Phthalate(DBP)	84-74-2	0.3	mg/kg	0.05	ND
Di (2-ethylhexyl) Phthalate(DEHP)	117-81-7	1.5	mg/kg	0.05	ND
Diisononyl phthalate + Diisodecyl phthalate (DINP + DIDP)	68515-48-0 and 26761-40-0	9	mg/kg	0.2	ND
Diallyl Phthalate (DAP)	131-17-9	0.01	mg/kg	0.01	ND
Conclusion					PASS

Sample 001

Simulant Used : Isooctane

Test Condition : 20°C 0.5hr(s)

<u>Test Item(s)</u>	<u>CAS NO.</u>	<u>Max. Permissible</u> <u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times		-	-	-	First
Area/volume		-	dm ² /kg	-	6.0
Benzylbutyl Phthalate(BBP)	85-68-7	30	mg/kg	0.05	ND
Dibutyl Phthalate(DBP)	84-74-2	0.3	mg/kg	0.05	ND
Di (2-ethylhexyl) Phthalate(DEHP)	117-81-7	1.5	mg/kg	0.05	ND
Diisononyl phthalate + Diisodecyl phthalate (DINP + DIDP)	68515-48-0 and 26761-40-0	9	mg/kg	0.2	ND
Diallyl Phthalate(DAP)	131-17-9	0.01	mg/kg	0.01	ND
Conclusion					PASS

Notes :

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

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments -Specific migration of heavy metal

Test Method : With reference to EN13130-1:2004, analysis was performed by ICP-OES.



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Test Report

No. TAOHG1802365501

Date: 07 Jun 2018

Page 4 of 6

Sample 001

Simulant Used : 3% Acetic Acid (W/V) Aqueous Solution

Test Condition : 40°C 2.0hr(s)

<u>Test Item(s)</u>	<u>Max. Permissible</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
	<u>Limit</u>			
Migration times	-	-	-	Third
Area/volume	-	dm ² /kg	-	6.0
Aluminium	1	mg/kg	0.1	ND
Barium	1	mg/kg	0.25	ND
Cobalt	0.05	mg/kg	0.01	ND
Copper	5	mg/kg	0.25	ND
Iron	48	mg/kg	0.25	ND
Lithium	0.6	mg/kg	0.5	ND
Manganese	0.6	mg/kg	0.25	ND
Nickel	0.02	mg/kg	0.01	ND
Zinc	5	mg/kg	0.5	ND
Conclusion				PASS

Notes :

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

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments - Phthalates

Test Method : Solvent extraction, analysis was performed by GC-MS.

<u>Test Item(s)</u>	<u>CAS NO.</u>	<u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>001</u>
Dibutyl Phthalate (DBP)	84-74-2	0.05	%	0.003	ND
Benzylbutyl Phthalate (BBP)	85-68-7	0.1	%	0.003	ND
Bis-(2-ethylhexyl) Phthalate (DEHP)	117-81-7	0.1	%	0.003	ND
Diisononyl Phthalate (DINP)	28553-12-0/ 68515-48-0	0.1	%	0.01	ND
Diisodecyl Phthalate (DIDP)	26761-40-0/ 68515-49-1	0.1	%	0.01	ND

Comment

PASS



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Commission Implementing Regulation (EU) 321/2011 amending Regulation (EU) 10/2011 of 14 January 2011-Bisphenol A

Test Method : With reference to Part II Section D2 of Testing Methods for Foodstuffs, Implements, Containers and Packaging, Toys, Detergents, JETRO, Japan External Trade Organization, 2009 (Dichloromethane extraction by ultrasonic bath). Analysis was performed by HPLC-MS.

<u>Test Item(s)</u>	<u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>001</u>
Bisphenol-A	★	mg/kg	0.1	ND
Conclusion				PASS

Notes :

★ = prohibited

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments - Residual vinyl chloride monomer

Test Method : In-house method (SHTC-CHEM-SOP-171-T), analysis was performed by HS-GC-MS.

<u>Test Item(s)</u>	<u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>001</u>
Vinyl chloride monomer	1	mg/kg	0.5	ND
Conclusion				PASS

Notes :

(1) The test was subcontracted to SGS Shanghai chemical lab.



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