

Test Report

No. TSNHG2001258601

Date: 07 Aug 2020

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HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD.
EASTERN INDUSTRIAL ZONE,NANGONG CITY,XINGTAI CITY,HEBEI,CHINA

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

SGS Job No. : TJHL2007004565CW - TJ
 Manufacturer : HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD.
 Country of Origin : CHINA
 Country of Destination : CHINA/EU/USA
 Date of Sample Received : 17 Jul 2020
 Testing Period : 17 Jul 2020 - 07 Aug 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
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments– 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
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 Bisphenol A	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 – Vinyl chloride monomer	PASS
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Phthalates	PASS



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



Reabeca Zhou
Approved Signatory

scan to see the report



TSNHG2001258601



SGS-CSTC Standards Technical Services (Tianjin) Co., Ltd.
Chemical Laboratory

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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TSN20-012586.001	translucent plastic gloves	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 1186-3:2002 aqueous food simulants 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>
10% Ethanol (V/V) Aqueous Solution	2.0hr(s)	70°C	10mg/dm ²	<3.0mg/dm ²
3% Acetic Acid (W/V) Aqueous Solution	2.0hr(s)	70°C	10mg/dm ²	<3.0mg/dm ²

Notes :

- (1) Analytical tolerance of aqueous simulants is 2 mg/dm².
- (2) Test condition & simulant were specified by client.
- (3) 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
 Test media: Distilled water
 No. of panelist: 6



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<u>Test Item(s)</u>	<u>Limit</u>	<u>001</u>
Test time (hr(s))	-	2.0
Test Temperature (°C)	-	70
Sensorial examination odour	2.5	0.0
Sensorial examination taste	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

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.

Sample 001

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

Test Condition : 70 °C 2.0 hr(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
Bis-(2-ethylhexyl) Phthalate(DEHP)	117-81-7	1.5	mg/kg	0.05	ND
Diisononyl phthalate + Diisodecyl phthalate (DINP+DIDP)	-	9.00	mg/kg	0.20	ND
Diallyl Phthalate(DAP)	131-17-9	0.01	mg/kg	0.01	ND

Notes :

Test condition & simulant were specified by client.



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Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments –Specific Migration of Bisphenol A

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

Sample 001

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

Test Condition : 70 °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 Bisphenol-A	0.05	mg/kg	0.01	ND

Notes :

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.

Sample 001

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

Test Condition : 70 °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
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
Zinc	5	mg/kg	0.5	ND
Aluminium	1	mg/kg	0.1	ND
Nickel	0.02	mg/kg	0.01	ND

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Notes :

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

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments –Vinyl chloride monomer

Test Method : SGS In house method, analysis was performed by HS-GC-MS.

<u>Test Item(s)</u>	<u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>001</u>
VCM(Vinyl Chloride Monomer)	1	mg/kg	0.5	ND

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	% (w/w)	0.003	ND
Benzylbutyl Phthalate (BBP)	85-68-7	0.1	% (w/w)	0.003	ND
Bis-(2-ethylhexyl) Phthalate (DEHP)	117-81-7	0.1	% (w/w)	0.003	ND
Diisononyl Phthalate (DINP)	28553-12-0/ 68515-48-0	0.1	% (w/w)	0.01	ND
Diisodecyl Phthalate (DIDP)	26761-40-0/ 68515-49-1	0.1	% (w/w)	0.01	ND



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