

Test Report

No. TAOHG2102133501

Date: 13 May 2021

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The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE EXAMINATION VINYL GLOVE POWDER-FREE NON-STERILE

SGS Job No. : QDHL2104502996CW - QD

Item No. : BLACK

PO No. : 20210428

Supplier : **Belix – Avenue de l'Espérance 41 – B – 6220 Fleurus**

Date of Sample Received : 30 Apr 2021

Testing Period : 30 Apr 2021 - 13 May 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).



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Result Summary :

Test Requested	Conclusion
(EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation-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
(EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation-Specific migration of primary aromatic amine (individual)	PASS
(EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation-Specific migration of bisphenol A(BPA)	PASS
(EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation -Specific migration of primary aromatic amine (total)	PASS
(EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation -Specific migration of heavy metal	PASS
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments - Residual vinyl chloride monomer	PASS
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments - Phthalates	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 Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TAO21-021335.001	Black 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)

(EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation-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;

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 001 Overall migration	Conclusion
3% Acetic acid (W/V) aqueous solution (First migration)	2.0hr(s)	70°C	10mg/dm ²	<3.0mg/dm ²	PASS
10% Ethanol (V/V) Aqueous Solution (First migration)	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.

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)	-	1
Temperature (°C)	-	20
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

(EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation-Specific migration of primary aromatic amine (individual)

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

Sample 001

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

Test Condition : 20 °C 1.0 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
2,4,5-Trimethylaniline(2,4,5-TMA)	0.002	mg/kg	0.002	ND
2,4-Toluenediamine(2,4-TDA)	0.002	mg/kg	0.002	ND
2-Methoxy-5-Methylaniline(2-M-5-MA)	0.002	mg/kg	0.002	ND
3,3'-Dimethylbenzidine(3,3'-DMB)	0.002	mg/kg	0.002	ND
4,4'-Diaminodiphenylether(4,4'-DPE)	0.002	mg/kg	0.002	ND
4,4'-Methylenedianiline(4,4'-MDA)	0.002	mg/kg	0.002	ND
4,4'-Methylenedi-o-toluidine(4,4'-MDoT)	0.002	mg/kg	0.002	ND
4-Aminobiphenyl(4-ABP)	0.002	mg/kg	0.002	ND
4-Chloro-Aniline(4-CA)	0.002	mg/kg	0.002	ND
4-Chloro-o-Toluidine(4-CoT)	0.002	mg/kg	0.002	ND
4-Methoxy-mphenylenediamine(4-M-mPDA)	0.002	mg/kg	0.002	ND



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Benzidine(BNZ)	0.002	mg/kg	0.002	ND
o-Anisidine(o-ASD)	0.002	mg/kg	0.002	ND
o-Toluidine(O-T)	0.002	mg/kg	0.002	ND
1,3-phenylenediamine	0.002	mg/kg	0.002	ND
2-naphthylamine	0.002	mg/kg	0.002	ND
o-aminoazotoluene	0.002	mg/kg	0.002	ND
2-Amino-4-nitrotoluene	0.002	mg/kg	0.002	ND
3,3'-dichlorobenzidine	0.002	mg/kg	0.002	ND
3,3'-dimethoxybenzidine	0.002	mg/kg	0.002	ND
4,4'-methylene-bis-(2-chloro-aniline)	0.002	mg/kg	0.002	ND
4,4'-thiodianiline	0.002	mg/kg	0.002	ND
4-amino azobenzene	0.002	mg/kg	0.002	ND
Conclusion				PASS

Notes :

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

(EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation-Specific migration of bisphenol A(BPA)

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

Sample 001

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

Test Condition : 20 °C 1.0 hr(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	-	-	-	First
Area/volume	-	dm ³ /kg	-	6.0
Specific migration of Bisphenol-A	0.05	mg/kg	0.01	ND
Conclusion				PASS

Notes :

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

(EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation -Specific migration of primary aromatic amine (total)

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



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

Test Condition : 20 °C 1.0 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	0.002	ND
Conclusion				PASS

Notes :

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

(EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation -Specific migration of heavy metal

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

Sample 001

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

Test Condition : 20 °C 1.0 hr(s)

Test Item(s)	Max. Permissible Limit	Unit	MDL	Test result
Migration times	-	-	-	First
Area/volume	-	dm ² /kg	-	6.0
Aluminium(Al)	1	mg/kg	0.1	ND
Barium (Ba)	1	mg/kg	0.25	ND
Cobalt (Co)	0.05	mg/kg	0.01	ND
Copper (Cu)	5	mg/kg	0.25	ND
Iron(Fe)	48	mg/kg	5	ND
Lithium (Li)	0.6	mg/kg	0.1	ND
Manganese(Mn)	0.6	mg/kg	0.1	ND
Zinc(Zn)	5	mg/kg	0.5	ND
Nickel(Ni)	0.02	mg/kg	0.01	ND
Arsenic(As)	ND	mg/kg	0.01	ND
Cadmium(Cd)	ND	mg/kg	0.002	ND
Chromium(Cr)	ND	mg/kg	0.01	ND



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Mercury(Hg)	ND	mg/kg	0.01	ND
Lead(Pb)	ND	mg/kg	0.01	ND
Antimony(Sb)	0.04	mg/kg	0.01	ND
Europium (Eu)	-	mg/kg	0.025	ND
Gadolinium(Gd)	-	mg/kg	0.025	ND
Lanthanum(La)	-	mg/kg	0.025	ND
Terbium(Tb)	-	mg/kg	0.025	ND
Europium (Eu)+ Gadolinium(Gd)+ Lanthanum(La)+ Terbium(Tb)	0.05	mg/kg	-	ND
Conclusion	PASS			

Notes :

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

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.

Test Item(s)	Limit	Unit	MDL	001
VCM(Vinyl Chloride Monomer)	1	mg/kg	0.5	ND
Conclusion	PASS			

Notes :

- The test was subcontracted to SGS Shanghai chemical lab.

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

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

Test Item(s)	CAS NO.	Limit	Unit	MDL	001
Dibutyl Phthalate (DBP)	84-74-2	0.05	%	0.003	ND
Benzylbutyl Phthalate (BBP)	85-68-7	0.1	%	0.003	ND
Di-(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



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Test Item(s)	CAS NO.	Limit	Unit	MDL	001
Diisodecyl Phthalate (DIDP)	26761-40-0/ 68515-49-1	0.1	%	0.01	ND
Comment	PASS				

Sample photo:



SGS authenticate the photo on original report only

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