

Test Report No.: 68.431.22.0147.01

Dated: 2022-08-24



Applicant : GUANGDONG KINGFA SCI.&TECH. CO., LTD.
NO.28 Delong Avenue, Shijiao Town, Qingcheng District,
Qingyuan City, Guangdong Province, China

Sample Description : Nitrile gloves

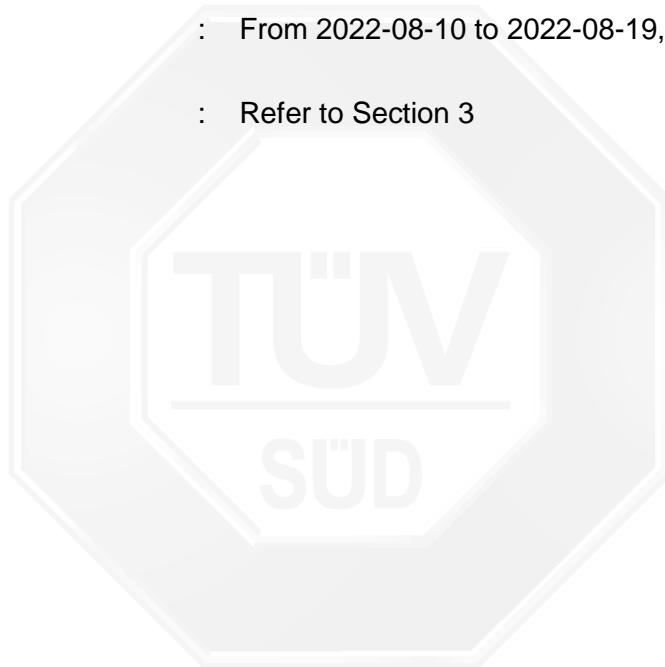
Style No. / Name / Design No. : BIO-G01

Supplier/Manufacturer : GUANGDONG KINGFA SCI.&TECH. CO., LTD.

Test Sample Receipt Date, Location : 2022-08-10, Shenzhen

Test Period, Location : From 2022-08-10 to 2022-08-19, Shenzhen

Test Result(s) : Refer to Section 3



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Purpose Of Examination / Conclusion:

Test Requested:	As specified by client, to test per the selected requirement(s) for the tested item(s) as stated in the Regulation (EC) No.1935/2004
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No.	Test Item(s)	Conclusion
1.	Overall Migration	Pass
2	Specific Migration of PAA	Pass
3	Specific Migration of PAAs	Pass
4	Specific Migration of Phthalates	Pass
5	Specific Migration of Butadiene (BU)	Pass
6.	N-Nitrosamines and N-Nitrosatable substances	Pass
7	Total Butadiene content	Pass
8	Phthalates Test	Pass

Remarks:

- (1) The results relate only to the items tested.
- (2) Samples are tested as received.
- (3) The test item and samples were specified by the client
- (4) "Pass" means the measured result is within a limit, even when extended by expanded uncertainty. "Fail" means the measured result is beyond a limit, even when extended by expanded uncertainty. "Inconclusive" means the measured result can be within or beyond a limit when extended by expanded uncertainty. The confidence level of the expanded uncertainty for "Pass", "Fail" and "Inconclusive" is 95%.

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
TÜV SÜD Group

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1. Description of the Test Sample:

Sample Description	Nitrile gloves
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2. List of Materials as identified by the Laboratory:

T. No.	Sample No.	Colour and Description	Photograph
T1	001	Blue nitrile rubber	



3. Test Result

3.1 Overall Migration

Test method: As specified in Regulation (EU) No. 10/2011 ANNEX III and V, test with reference to:
 EN 1186-1:2002 (Guide to the selection of conditions and test methods for overall migration)
 EN 1186-2:2002 (Oil by Total Immersion method)
 EN 1186-3:2002 (Total Immersion method)
 [Reporting Limit: 3mg/dm²]

TEST ITEM	TEST CONDITIONS	RESULTS [mg/dm ²]			LIMIT [mg/dm ²]
		SAMPLE 001 1 st Migration	SAMPLE 001 2 nd Migration	SAMPLE 001 3 rd Migration	
3% Acetic acid	40°C for 0.5 Hour	5.0	ND	ND	<10
10% Ethanol	40°C for 0.5 Hour	ND	ND	ND	<10
Rectified olive oil	40°C for 0.5 Hour	3.5	ND	ND	<10
Conclusion:		Pass*			--

Note 1. "°C" denotes degree Celsius

2. "<" denotes less than

3. "mg/dm²" denotes milligram per square decimeter

4. "ND" denotes below the Report Limit

5. The specification was quoted from Regulation (EU) No. 10/2011 and its amendments

6. "*" denotes the results of second migration should lower than first migration, the result of third migration should lower than second migration.

3.2 Specific Migration of PAA

Test method: with reference to EN 13130-1:2004, follow by Ultraviolet and visible spectrophotometry (UV-Vis).

Test Conditions: 3% Acetic Acid: 40 °C for 0.5 Hour

TEST ITEM	RESULT [mg/kg foodstuff]			Reporting limit [mg/kg]	LIMIT [mg/kg]
	SAMPLE 001 1 st Migration	SAMPLE 001 2 nd Migration	SAMPLE 001 3 rd Migration		
Primary Aromatic Amine	ND	ND	ND	<0.01	<0.01
Conclusion:	Pass	Pass	Pass	--	--

Note 1. "°C" denotes degree Celsius

2. "<" denotes less than

3. "mg/kg" denotes milligram per kilogram

4. "ND" denotes below the Reporting limit

5. The specification was quoted from Regulation (EU) No. 10/2011 and its amendments

3.3 Specific Migration of PAAs

Test method: with reference to EN 13130-1:2004, follow by Liquid chromatography tandem mass spectrometer (LC-MS/MS). [Reporting Limit:0.002 mg/kg]

Test Conditions: 3% Acetic Acid: 40 °C for 0.5 Hour

TEST ITEM	RESULTS [mg/kg foodstuff]			LIMIT [mg/kg]
	SAMPLE 001 1 st Migration	SAMPLE 001 2 nd Migration	SAMPLE 001 3 rd Migration	
4-Aminobiphenyl (4-ABP)	ND	ND	ND	<0.002
Aniline (ANL)	ND	ND	ND	<0.002
o-Anisidine (o-ASD)	ND	ND	ND	<0.002
Benzidine (BNZ)	ND	ND	ND	<0.002
4-Chloro-Aniline (4-CA)	ND	ND	ND	<0.002
4-Chloro-o-Toluidine (4-CoT)	ND	ND	ND	<0.002
2,4-Dimethylaniline (2,4-DMA)	ND	ND	ND	<0.002
4,4'-Diaminodiphenylether (4,4'-DPE)	ND	ND	ND	<0.002
4,4'-Methylenedianiline (4,4'-MDA)	ND	ND	ND	<0.002
4,4'-Methylenedi-o-toluidine (4,4'-MDoT)	ND	ND	ND	<0.002
2-Methoxy-5-Methylaniline (2-M-5-MA)	ND	ND	ND	<0.002
m-Phenylenediamine (m-PDA)	ND	ND	ND	<0.002
4-Methoxy-mphenylenediamine (4-M-mPDA)	ND	ND	ND	<0.002
o-Toluidine (o-T)	ND	ND	ND	<0.002
2,4-Toluenediamine (2,4-TDA)	ND	ND	ND	<0.002
3,3-Dimethylbenzidine (3,3-DMB)	ND	ND	ND	<0.002
2,4,5-Trimethylaniline (2,4,5-TMA)	ND	ND	ND	<0.002
2,6-Toluenediamine (2,6-TDA)	ND	ND	ND	<0.002
2,6-Dimethylaniline (2,6-DMA)	ND	ND	ND	<0.002
p-Phenylenediamine (p-PDA)	ND	ND	ND	<0.002
1,5-Diaminenaphthalene (1,5-DAN)	ND	ND	ND	<0.002
2-naphthylamine	ND	ND	ND	<0.002
o-aminoazotoluene	ND	ND	ND	<0.002
5-nitro-o-toluidine	ND	ND	ND	<0.002
3,3'-dichlorobenzidine	ND	ND	ND	<0.002
3,3'-dimethoxybenzidine	ND	ND	ND	<0.002
4,4'-methylene-bis-(2-chloro-aniline)	ND	ND	ND	<0.002
4,4'-thiodianiline	ND	ND	ND	<0.002
4-amino azobenzene	ND	ND	ND	<0.002
Conclusion:	Pass	Pass	Pass	--

Note 1. "°C" denotes degree Celsius

2. "<" denotes less than

3. "mg/kg" denotes milligram per kilogram

4. "ND" denotes below the Report Limit

5. The specification was quoted from Regulation (EU) No. 10/2011 and its amendments

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3.4 Specific Migration of Phthalates

Test method: As specified in Regulation (EU) No. 10/2011 ANNEX III and V, and followed by gas chromatography/Mass Spectrometry (GC-MS) analysis.

Test Conditions: 95% Ethanol: 40 °C for 0.5 Hour

TEST ITEM	RESULT [mg/kg foodstuff]			Reporting limit [mg/kg]	LIMIT [mg/kg]
	SAMPLE 001 1 st Migration	SAMPLE 001 2 nd Migration	SAMPLE 001 3 rd Migration		
Dibutyl phthalate (DBP)	ND	ND	ND	<0.30	0.3
benzyl butyl phthalate (BBP)	ND	ND	ND	<1.0	30
Bis (2-ethylhexyl) phthalate (DEHP)	ND	ND	ND	<0.30	1.5
adipic acid, bis(2-ethylhexyl) ester (DEHA)	ND	ND	ND	<1.0	18
Bis(2-Ethylhexyl) Terephthalate (DEHTP)	ND	ND	ND	<1.0	60
DINP+DIDP	ND	ND	ND	<2.0	9
Conclusion:	Pass*			--	--

Note 1. "°C" denotes degree Celsius

2. "<" denotes less than

3. "mg/kg" denotes milligram per kilogram

4. "ND" denotes below the Reporting limit

5. The specification was quoted from Regulation (EU) No. 10/2011 and its amendments

6. "*" denotes the results of second migration should lower than first migration, the result of third migration should lower than second migration.



3.5 Specific Migration of Butadiene (BU)

Test method: with reference to EN 13130-1:2004 and CEN/TS 13130-15:2005, follow by Headspace-Gas Chromatography Mass Spectrometry.

Test Conditions: 3% Acetic Acid: 40 °C for 0.5 Hour

TEST ITEM	RESULT [mg/kg foodstuff]			Reporting limit [mg/kg]	LIMIT [mg/kg]
	SAMPLE 001 1 st Migration	SAMPLE 001 2 nd Migration	SAMPLE 001 3 rd Migration		
Butadiene	ND	ND	ND	<0.01	<0.01
Conclusion:	Pass	Pass	Pass	--	--

Note 1. "°C" denotes degree Celsius

2. "<" denotes less than

3. "mg/kg" denotes milligram per kilogram

4. "ND" denotes below the Reporting limit



3.6 N-Nitrosamines and N-Nitrosatable substances

Test Method: As per EN12868:2017, analyzed by high performance liquid chromatography with mass spectrometer detector (HPLC-MS-MS)

Test Conditions: 40 °C for 24 Hours

Items	Results [mg/kg]	Limit
	Sample 001	
[Amines] N-nitrosodimethylamine (NDMA)	<0.001	-
[Amines] N-nitrosodiethylamine (NDEA)	<0.001	-
[Amines] NPYR + NMPhA	<0.001	-
[Amines] N-nitrosomorpholine (NMOR)	<0.001	-
[Amines] N-nitrosodipropylamine (NDPA)	<0.001	-
[Amines] N-nitrosopiperidine (NPIP)	<0.001	-
[Amines] N-nitroso N-ethyl N-phenylamine (NEPhA)	<0.001	-
[Amines] N-nitrosodibutylamine (NDBA)	<0.001	-
[Amines] N-nitrosodibenzylamine (NDBzA)	<0.001	-
[Amines] N-nitrosodiisononylamine (NDiNA)	<0.001	-
Sum of N-Nitrosamines	<0.01	<0.01
[Satable] N-nitrosodimethylamine (NDMA)	<0.01	-
[Satable] N-nitrosodiethylamine (NDEA)	<0.01	-
[Satable] NPYR + NMPhA	<0.01	-
[Satable] N-nitrosomorpholine (NMOR)	<0.01	-
[Satable] N-nitrosodipropylamine (NDPA)	<0.01	-
[Satable] N-nitrosopiperidine (NPIP)	<0.01	-
[Satable] N-nitroso N-ethyl N-phenylamine (NEPhA)	<0.01	-
[Satable] N-nitrosodibutylamine (NDBA)	<0.01	-
[Satable] N-nitrosodibenzylamine (NDBzA)	<0.01	-
[Satable] N-nitrosodiisononylamine (NDiNA)	<0.01	-
Sum of N-Nitrostable	<0.1	<0.1
Conclusion	Pass	-

Note:

1. "mg/kg" denotes milligram per kilogram
2. "<" denotes less than

3.7 Total Butadiene content

Test method: with reference to EN 13130-1:2004 and EN 13130-4:2004, follow by Headspace-Gas Chromatography Flame Ionization Detector (GC-FID).

TEST ITEM	RESULTS [mg/kg]	MAXIMUM PERMISSIBLE LIMIT [mg/kg]
	SAMPLE 001	
Total butadiene content	<0.2	1.0
Conclusion	Pass	-

Note 1. "<" denotes less than

2. "mg/kg" denotes milligram per kilogram

3.8 Phthalates Test

Solvent extraction in chloroform, followed by GC-MS
[Reporting Limit = 0.005%]

Test Items	CAS No.	Results [%]	Limit [%]
		Sample 001	
Benzyl butyl Phthalate, (BBP)	85-68-7	<0.005	<0.1
Di-isodecyl Phthalate, (DIDP)	26761-40-0 , 68515-49-1	<0.005	<0.1
Bis (2-ethylhexyl) Phthalate, (DEHP)	117-81-7	<0.005	<0.1
Di-isononyl Phthalate, (DINP)	28553-12-0 , 68515-48-0	<0.005	<0.1
Di-n-butyl Phthalate, (DnBP)	84-74-2	<0.005	<0.05
Conclusion		Pass	-

Note 1. "<" denotes less than

2. "%" denotes percent by weight

3. The specification was quoted from regulation (EU) No. 10/2011 and its amendment (EU) No. 2020/1245.

-- END OF TEST REPORT--