

Test Report No.: 68.431.24.9004.01

Dated: 2024-02-02



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. / Model No. / Design No. : KG-1101

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

Test Sample Receipt Date, Location : 2024-01-11, Shenzhen

Test Period, Location : From 2024-01-11 to 2024-02-01, 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	Specific Migration of 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 glove	





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 1186-2:2022 (Test methods for overall migration in vegetable oils)
 EN 1186-3:2022 (Test methods for overall migration in evaporable simulants)
 [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 2 Hours	5.9	ND	ND	<10
10% Ethanol	40°C for 2 Hours	ND	ND	ND	<10
Rectified olive oil	40°C for 2 Hours	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 2 Hours

TEST ITEM	RESULT [mg/kg]			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 2 Hours

TEST ITEM	CAS No.	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)	92-67-1	ND	ND	ND	<0.002
Aniline (ANL)	62-53-3	ND	ND	ND	<0.002
o-Anisidine (o-ASD)	90-04-0	ND	ND	ND	<0.002
Benzidine (BNZ)	92-87-5	ND	ND	ND	<0.002
4-Chloro-Aniline (4-CA)	106-47-8	ND	ND	ND	<0.002
4-Chloro-o-Toluidine (4-CoT)	95-69-2	ND	ND	ND	<0.002
2,4-Dimethylaniline (2,4-DMA)	95-68-1	ND	ND	ND	<0.002
4,4'-Diaminodiphenylether (4,4'-DPE)	101-80-4	ND	ND	ND	<0.002
4,4'-Methylenedianiline (4,4'-MDA)	101-77-9	ND	ND	ND	<0.002
4,4'-Methylenedi-o-toluidine (4,4'-MDoT)	838-88-0	ND	ND	ND	<0.002
2-Methoxy-5-Methylaniline (2-M-5-MA)	120-71-8	ND	ND	ND	<0.002
m-Phenylenediamine (m-PDA)	108-45-2	ND	ND	ND	<0.002
4-Methoxy-mphenylenediamine (4-M-mPDA)	615-05-4	ND	ND	ND	<0.002
o-Toluidine (o-T)	95-53-4	ND	ND	ND	<0.002
2,4-Toluediamine (2,4-TDA)	95-80-7	ND	ND	ND	<0.002
3,3-Dimethylbenzidine (3,3-DMB)	119-93-7	ND	ND	ND	<0.002
2,4,5-Trimethylaniline (2,4,5-TMA)	137-17-7	ND	ND	ND	<0.002
2,6-Toluediamine (2,6-TDA)	823-40-5	ND	ND	ND	<0.002
2,6-Dimethylaniline (2,6-DMA)	87-62-7	ND	ND	ND	<0.002
p-Phenylenediamine (p-PDA)	106-50-3	ND	ND	ND	<0.002
1,5-Diaminenaphthalene (1,5-DAN)	2243-62-01	ND	ND	ND	<0.002
2-naphthylamine	91-59-8	ND	ND	ND	<0.002
o-aminoazotoluene	97-56-3	ND	ND	ND	<0.002
5-nitro-o-toluidine	99-55-8	ND	ND	ND	<0.002
3,3'-dichlorobenzidine	91-94-1	ND	ND	ND	<0.002
3,3'-dimethoxybenzidine	119-90-4	ND	ND	ND	<0.002
4,4'-methylene-bis-(2-chloro-aniline)	101-14-4	ND	ND	ND	<0.002
4,4'-thiodianiline	139-65-1	ND	ND	ND	<0.002
4-amino azobenzene	60-09-3	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 2 Hours

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	<0.1	0.12
benzyl butyl phthalate (BBP)	ND	ND	ND	<0.1	6
Bis (2-ethylhexyl) phthalate (DEHP)	ND	ND	ND	<0.1	0.6
adipic acid, bis(2-ethylhexyl) ester (DEHA)	ND	ND	ND	<1.0	18
Bis(2-Ethylhexyl) Terephthalate (DEHTP)	ND	ND	ND	<1.0	/
DINP+DIDP	ND	ND	ND	<0.5	1.8
Diallyl phthalate (DAP)	ND	ND	ND	<0.01	0.01
Sum of (DBP*5+DIBP*4+BBP*0.1+DEHP*1)	ND	ND	ND	<0.1	0.6
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 2 Hours

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 Specific Migration of N-Nitrosamines and N-Nitrosatable Substances

Test method: With reference to EN 13130-1:2004, followed by Liquid Chromatography with Tandem Mass Spectrometry Detection (LC-MS/MS) analysis.

Test Conditions: 3% acetic acid 40 °C for 2 Hours

Test Item	CAS No.	RESULT [mg/kg]					
		SAMPLE 001 1 st Migration		SAMPLE 001 2 nd Migration		SAMPLE 001 3 rd Migration	
		N-Nitrosamines	N-Nitrosatable substances	N-Nitrosamines	N-Nitrosatable substances	N-Nitrosamines	N-Nitrosatable substances
N-Nitrosodimethylamine (NDMA)	62-75-9	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
N-nitrosomethylethylamine (NMEA)	10595-95-6	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
N-Nitrosodiethylamine (NDEA)	55-18-5	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
N-Nitrosopyrrolidine (NPYR)	930-55-2	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
N-nitrosomorpholine (NMOR)	59-89-2	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
N-Nitrosodipropylamine (NDPA)	621-64-7	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
N-nitrosopiperidine (NPIP)	100-75-4	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
N-nitrosodibutylamine (NDBA)	924-16-3	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
N-nitrosodibenzylamine (NDBzA)	5336-53-8	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
N-nitroso N-methyl N-phenylamine (NMPPhA)	614-00-6	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
N-nitroso N-ethyl N-phenylamine (NEPhA)	612-64-6	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
N-nitrosodiisobutylamine (NDiBA)	997-95-5	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
N-nitrosodiisnonylamine (NDiNA)	1207995-62-7	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
Sum of above	--	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1
Limit	--	<0.01	<0.1	<0.01	<0.1	<0.01	<0.1

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	<0.005	Sum of DIDP, DEHP, DINP and DBP: 5
Bis (2-ethylhexyl) Phthalate, (DEHP)	117-81-7	<0.005	
Di-isononyl Phthalate, (DINP)	28553-12-0	<0.005	
Di-n-butyl Phthalate, (DnBP)	84-74-2	<0.005	
Sum of DIDP, DEHP, DINP, DnBP	-	<0.02	
Conclusion		Pass	-

- Note 1. "<" denotes less than
 2. "%" denotes percent by weight
 3. The specification was quoted from Regulation (EU) No. 10/2011

-- END OF TEST REPORT--