

XIAMEN BETTER SILICONE RUBBER CO.,LTD

2F, NO. 165, TONG'AN PARK, INDUSTRY CLUSTER ZONE, TONG'AN DISTRICT, XIAMEN CITY, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : NITRILE RUBBER SEAL
Style / Item No. : GBM/CRYSTAL FLOAT SEAL V1—D183901
Sample Receiving Date : Jan. 8, 2019
Test Performing Date : Jan. 8, 2019 to Jan. 23, 2019
Test Performed : Selected test(s) as requested by applicant
Test Result(s) : For further details, please refer to the following page(s)

Signed for and on behalf of
Xiamen Branch, SGS-CSTC Co., Ltd.



Sharky Xia
Approved Signatory



SGS-CSTC Inspection & Testing Services Co., Ltd.
Xiamen Branch Testing Center Handlines

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Part 1: SGS Ref. No. is CANHG1822837101. This test was subcontracted to Guangzhou Branch, SGS-CSTC Co., Ltd.

Result Summary :

Test Requested	Conclusion
FDA 21 CFR 177.1210–Chloroform-soluble extractive residues	See Results
Council of Europe Resolution AP (2004) 4 – Specific Migration of Primary Aromatic Amine	PASS
Council of Europe Resolution AP (2004) 4 – Specific Migration of N-Nitrosamines and N-Nitrosatable substances	PASS

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	CAN18-228371.001	Black rubber	NBR

FDA 21 CFR 177.1210–Chloroform-soluble extractive residues

Test Method : With reference to US FDA 21 CFR 177.1210.

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 001</u>
8% Ethanol	24.0hr(s)	120°F	50ppm	39ppm
Distilled Water	24.0hr(s)	120°F	50ppm	42ppm

Notes :

1. ppm = mg/kg = milligram per kilogram of foodstuff in contact with
2. Result(s) was/were calculated based on the 1inch² to 10mL migration ratio (contact surface of the sealing article : volume of stimulant).

Council of Europe Resolution AP (2004) 4 – Specific Migration of Primary Aromatic Amine

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 13130-1:2004 for selection of test method and BfR Recommendation XXI. Analysis was performed by UV-Vis.



Sample 001

Simulant Used : 3% Acetic Acid (W/V) Aqueous Solution
 Test Condition : 40°C 240.0hr(s)

<u>Test Item(s)</u>	<u>Max. Permissible Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times	-	-	-	1st
Area/Volume	-	dm ² /kg	-	6.0
Specific migration of primary aromatic amine	0.010	mg/kg	0.010	ND
Comment				PASS

Notes :

1. mg/kg = milligram per kilogram of foodstuff in contact with
2. °C = degree Celsius
3. MDL=Method Detection Limit
4. ND = Not Detected(less than MDL)

Council of Europe Resolution AP (2004) 4 – Specific Migration of N-Nitrosamines and N-Nitrosatable substances

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 EN13130-1:2004 for selection of test methods; analysis was performed by LC-MS-MS.

Sample 001

Simulant Used : 3% Acetic acid (W/V) aqueous solution
 Test Condition : 40°C 240.0hr(s)

<u>Test Item(s)</u>	<u>Max. Permissible Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times	-	-	-	1st
Area/Volume	-	dm ² /kg	-	6.0
Specific migration of N-Nitrosamines	0.01	mg/kg	0.010	ND
Specific migration of N-Nitrosatable substances	0.1	mg/kg	0.10	ND
Comment				PASS



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Notes :

1. N-Nitrosamines tested : N-nitrosodimethylamine (NDMA), N-nitrosodiethylamine (NDEA), N-nitrosodipropylamine (NDPA), N-nitrosodibutylamine (NDBA), N-nitrosopiperidine (NPIP), N-nitrosopyrrolidine (NPYR), N-nitrosomorpholine (NMOR), N-nitrosodibenzylamine (NDBzA), N-nitroso-N-methyl-N-phenylamine (NMPPhA), N-nitroso-N-ethyl-N-phenylamine (NEPhA), N-nitrosodiisononylamine (NDiNA) and N-Nitrosodiisobutylamine (NDiBA).
2. mg/kg = milligram per kilogram of foodstuff in contact with
3. MDL=Method Detection Limit
4. ND = Not Detected(less than MDL)

Sample photo(s):



CANHG1822837101

CAN18-228371.001



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Part 2: SGS Ref. No. is CANHG1900679201. This test was subcontracted to Guangzhou Branch, SGS-CSTC Co., Ltd.

Result Summary :

Test Requested

Conclusion

FDA 21 CFR 177.2600–Total extractive residues

PASS

Council of Europe Resolution AP (2004) 4 – Overall migration

PASS

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	CAN19-006792.001	Black rubber	NBR

FDA 21 CFR 177.2600–Total extractive residues

Test Method : With reference to US FDA 21 CFR 177.2600.

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 001</u>	<u>Comment</u>
Distilled Water	7.0hr(s)	Reflux temperature	20mg/sq. in	<0.5mg/sq. in	PASS
Succeeding Extraction	2.0hr(s)	Reflux temperature	1mg/sq. in	<0.5mg/sq. in	PASS
n-Hexane	7.0hr(s)	Reflux temperature	175mg/sq. in	24.2mg/sq. in	PASS
Succeeding Extraction	2.0hr(s)	Reflux temperature	4mg/sq. in	3.2mg/sq. in	PASS

Notes :

mg/inch²= milligram per square inch

Council of Europe Resolution AP (2004) 4 – 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>	<u>Comment</u>
20% Ethanol (V/V) Aqueous Solution	240.0hr(s)	40°C	10mg/dm ²	4.6mg/dm ²	PASS



Notes :

1. mg/dm² = milligram per square decimeter
mg/kg = milligram per kilogram of foodstuff in contact with
2. °C = degree Celsius
3. Analytical tolerance of aqueous simulants is 2mg/dm² or 12mg/kg
4. Analytical tolerance of fatty food simulants is 3mg/dm² or 20mg/kg

Sample photo(s):



CANHG1900679201

CAN19-006792.001

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End of Report

