

GRAND SOURCING (XIAMEN) CO., LTD
RM 8032-33, NO. 350, CHANGLE ROAD, HULI DISTRICT, XIAMEN, FUJIAN, CHINA

Sample Description : DISPOSABLE MOUTH GUARD

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

SGS Ref No. : CANHG2017762401
Sample Receiving Date : Oct 12, 2020
Test Performing Date : Oct 12, 2020 to Oct 22, 2020
Test Performed : Selected test(s) as requested by applicant
Test Result(s) : For further details, please refer to the following page(s)



SGS-CSTC Shenzhen Technical Services Co., Ltd.
Xiamen Branch Testing Center Hardlines

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Result Summary :

Test Requested	Conclusion
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments– Overall migration	See Results
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004– Sensorial examination odour and taste test	See Results
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Specific Migration of Ethylene glycol & Diethylene glycol	See Results
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments– Specific Migration of Antimony	See Results
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments -Specific Migration of Acetaldehyde	See Results
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Specific Migration of Terephthalic Acid	See Results
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments– Specific Migration of Heavy Metal	See Results

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



Beck Hong
 Authorized Signatory



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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	CAN20-177624.001	Transparent plastic sheet	PET

**Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004,
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;
or EN 1186-14:2002 substitute test.

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 001 Overall Migration</u>
3% Acetic Acid (W/V) Aqueous Solution	2.0hr(s)	70°C	10mg/dm ²	<3.0mg/dm ²
10% Ethanol (V/V) Aqueous Solution	2.0hr(s)	70°C	10mg/dm ²	<3.0mg/dm ²
95% Ethanol	2.0hr(s)	60°C	10mg/dm ²	<3.0mg/dm ²
Isooctane	0.5hr(s)	40°C	10mg/dm ²	<3.0mg/dm ²

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
5. Report the third 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 DIN10955:2004,direct contact method.
No. of panelist:6

<u>Test Item(s)</u>	<u>Limit</u>	<u>001</u>
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Test media	-	Distilled water
Test Temperature (°C)	-	40
Test time (hr)	-	2
Sensorial examination odour (Point scale)	2.5	0.0
Sensorial examination taste (Point scale)	2.5	0.0

Notes :

- Intensity scale (rounded at 0.5):
- 0 – no perceptible difference
 - 1 – just perceptible difference
 - 2 – slight difference
 - 3 – marked difference
 - 4 – strong difference

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Specific Migration of Ethylene glycol & Diethylene glycol

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&EN13130-7:2004 for selection of test methods; analysis was performed by GC-FID.

Sample 001

Simulant Used : 3% Acetic Acid (W/V) Aqueous Solution
 Test Condition : 40°C 2.0hr(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
Ethylene glycol and Diethylene glycol(As Ethylene glycol)	30	mg/kg	3	ND

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)



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Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments– Specific Migration of Antimony

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 ICP-MS.

Sample 001

Simulant Used : 3% Acetic Acid (W/V) Aqueous Solution
 Test Condition : 40°C 2.0hr(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
Extractable Antimony	0.04	mg/kg	0.01	ND

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)

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments -Specific Migration of Acetaldehyde

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 method, analysis was performed by HPLC-DAD.

Sample 001

Simulant Used : 3% Acetic acid (W/V) aqueous solution
 Test Condition : 40°C 2.0hr(s)

<u>Test Item(s)</u>	<u>Max. Permissible</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
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	<u>Limit</u>			
Migration times	-	-	-	1st
Area/Volume	-	dm ² /kg	-	6.0
Specific Migration of Acetaldehyde	6.0	mg/kg	1.0	ND

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)

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Specific Migration of Terephthalic Acid

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 method, analysis was performed by HPLC-DAD.

Sample 001

Simulant Used : 3% Acetic Acid (W/V)
 Test Condition : 40°C 2.0hr(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
Terephthalic Acid	7.5	mg/kg	1.0	ND

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)

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments– Specific Migration of Heavy Metal



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 method, analysis was performed by ICP-OES.

Sample 001

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

Test Condition : 40°C 2.0hr(s)

Test Item(s)	Max. Permissible Limit	Unit	MDL	Test result
Migration times	-	-	-	1st
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
Aluminum	1	mg/kg	0.1	ND
Nickel	0.02	mg/kg	0.01	ND

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)

Remark: Limit = Reference limit. The test sample is out of scope of the standard.
 This test was subcontracted to Guangzhou Branch, SGS-CSTC Co., Ltd.
 This test report is to supersede No. XMHL2010010107CW test report which was issued on Oct 22, 2020. And the original test reports (paper and electronic) are invalid.



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Sample photo(s):



CANHG2017762401

CAN20-177624.001

The testing report/certificate only refers to the sample(s) tested.

End of Report

