

TO WHOM IT MAY CONCERN

Date: 10.02.2021

This is to put on record that Product manufactured by M/s Zenith Industrial Rubber Products Pvt. Ltd. Is declared that our product with code SI40120F in any colour is compliant to:

- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food. This is documented with test report nr. GGN/H(FCM)/16/000037 (dated 28-01-2016), attached to this statement, stating the positive result of the migration test according 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 (1st Migration) and EN 1186-3:2002 aqueous food simulants by total immersion method;
- US FDA 21.CFR.177.2600. This is documented with test report nr. TUV(I)/3455/15-16/0081500853 (dated 19-08-2015), attached to this statement, stating the positive result of the US-FDA test as per 21.CFR.177.2600 (Determination of Amount if Extractives);
- USP-6 standard.

For Zenith Industrial Rubber Products Pvt. Ltd.

Authorized Signatory

Mr. Mohan L. Mahajan

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General Manager - Technical





Note: (1) General Terms & Conditions as mentioned overleaf, (2) The results relate only to the items tested, (3) The test report shall not be reproduced except in full without the written approval of the laboratory, (4) For details of the accredited scope please contact the laboratory or Accreditation body



Company Name : Zenith Industrial Rubber Products Pvt. Ltd.

Address : Plot No. C-15, C-16, C-17, Dombivli Industrial Estate,

Phase-I, Dombivli (East), Dist. Thane - 421203

Contact Person : Mr. Keshavlal Koiri

Tested Sample : Received on 2016.01.11 at 3:09 p.m.

Test Period : 2016.01.13 to 2016.01.28

Sample Description : Silicone Food Grade Rubber Sheet, SI 40120 F, Translucent

Colour : Translucent

Objectives of Examination : 1. Sensory Verification (Transfer of Taste and Odour/Smell)

2. Overall migration

3. Specific migration of formaldehyde

Note: The submitted sample(s) is/are Not Drawn by the Laboratory

Remarks:

- 1. Sample(s) is/are tested as on-received basis.
- 2. Test(s) performed as requested by Applicant.

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3. Conclusion of test "Sensory Verification" was drawn as per contemporary & accepted industrial practice.

4. Selections of simulants & test conditions were done taking into account the worst foreseeable conditions of use of the finished product.

Prepared By

Sourav Bhattacharya Report Reviewer Authorized By

Anuradha Dhamija Authorized Signatory

Please Contact:

For any technical issues: Anuradha Dhamija at Anuradha.Dhamija@tuv-sud.in

For any complaint: Krishna Deori at Krishna.Deori@tuv-sud.in

By accepting this document the customer hereby agrees and accepts the 'Terms & Conditions' and the relevant 'Testing & Certification Regulations' of TUV SUD South Asia

Put 1 td, which are available at Company's website at the link-

Pvt. Ltd. which are available at Company's website at the linkhttp://www.tuv-sud.in/in-en/resource-centre/terms-and-conditions

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Material List/List of Materials (As confirmed by Applicant)

Component No. Component Description		Material	Colour
Α	Silicone Food Grade Rubber	Silicone	Translucent
	Sheet		

Sampling Plan (As requested by Applicant)

S. No.	Test	Component No.
1.	Sensory Verification (Transfer of Taste and Odour/Smell)	A
2.	Overall migration	A
3.	Specific migration of formaldehyde	A

Summary of Test Result(s)

S. No.	Test	Conclusion (Pass/Fail)
1.	Sensory Verification (Transfer of Taste and Odour/Smell)	Pass
2.	Overall migration	Pass
3.	Specific migration of formaldehyde	Pass



Test Results:-

(Test No. 1-i) Sensory verification of Odour/Smell

Test Specification(s)/Regulation(s): Regulation (EC) No. 1935/2004 & Council of Europe Resolution ResAP (2004) 5 on silicones to be used for food contact applications;

Test method adopted: DIN 10955:2004;

Simulant(s) used: Distilled water;

Test condition(s): 100 °C or reflux for 4 hours.

Component No.	Test Parameter	Result (Grade)	Compliance Requirement/Limit Max.	Conclusion (Pass/Fail) (Refer Remark 3 on Page No. 2)
Α	Rating	1	Less than 2.5	Pass

Note:

(Intermediate grades are allowed)

- 0 = no perceptible difference in odour;
- 1 = just perceptible difference in odour (still difficult to define);
- 2 = slight difference in odour;
- 3 = marked difference in odour;
- 4 = strong difference in odour.

(Test No. 1-ii) Sensory verification of Taste

Test Specification(s)/Regulation(s): Regulation (EC) No. 1935/2004 & Council of Europe Resolution ResAP (2004) 5 on silicones to be used for food contact applications;

Test method adopted: DIN 10955:2004;

Simulant(s) used: Distilled water;

Test condition(s): 100 °C or reflux for 4 hours.

Component No.	Test Parameter	Result (Grade)	Compliance Requirement/Limit Max.	Conclusion (Pass/Fail) (Refer Remark 3 on Page No. 2)
A	Rating	0	Less than 2.5	Pass

Note:

(Intermediate grades are allowed)

- 0 = no perceptible difference in taste;
- 1 = just perceptible difference in taste (still difficult to define);
- 2 = slight difference in taste;
- 3 = marked difference in taste;
- 4 = strong difference in taste.



(Test No. 2) Overall migration

Test Specification(s)/Regulation(s): Council of Europe Resolution ResAP (2004) 5 on silicones to be used for food contact applications;

Test method(s) adopted: With reference to EN 1186-3:2002 (for 3 % acetic acid) & EN 1186-14:2002 (for 95 % ethanol and iso-octane);

Simulant(s) used: Refer below;

Test condition(s): Refer below (Note: Tests conducted under repeat use conditions).

S.No.	Simulant used	Test condition(s)	Component No.	Result (mg/dm²)	Compliance Requirement/Limit Max. (mg/dm²)	Conclusion (Pass/Fail)
1.	3 % acetic	100 °C or reflux for 4 hours	А	ND	10	Pass
2.	95 % ethanol	60 °C for 6 hours	Α	ND	10	Pass
3.	Iso-octane	60 °C for 4 hours	Α	ND	10	Pass
Overall Conclusion (Pass/Fail)						Pass

Limit of Quantification: 2.0 mg/dm²

<u>Note</u>: (1) "mg/dm²" denotes milligram per square decimetre; (2) "°C" denotes degree Celsius; (3) "%" denotes per cent; (4) "ND" denotes Not Detected.

(Test No. 3) Specific migration of formaldehyde (CAS No. 50-00-0)

Test Specification(s)/Regulation(s): Council of Europe Resolution ResAP (2004) 5 on silicones to be used for food contact applications;

Test method(s) adopted: With reference to EN 13130-1:2004 followed by analysis as per DD CEN/TS 13130-23:2005;

Simulant(s) used: Refer below;

Test condition(s): Refer below (Note: Tests conducted under repeat use conditions).

S.No. 1.	Simulant used 3 % acetic acid	Test condition(s) 100 °C or reflux for 4 hours	Component No.	Result (mg/kg)	Compliance Requirement/Limit Max. 15 mg/kg	Conclusion (Pass/Fail) Pass
2.	95 % ethanol	60 °C for 6 hours	A	ND	15 mg/kg	Pass
3.	Iso-octane	60 °C for 4 hours	│A usion (Pass/Fai	ND	15 mg/kg	Pass Pass

Limit of Quantification: 10.0 mg/kg

Note: (1) "mg/dm²" denotes milligram per square decimetre; (2) "°C" denotes degree Celsius; (3) "%" denotes per cent; (4) "ND" denotes Not Detected.

---- END OF THE TEST REPORT ---

Note: (1) General Terms & Conditions as mentioned overleaf, (2) The results relate only to the items tested, (3) The test report shall not be reproduced except in full without the written approval of the laboratory, (4) For details of the accredited scope please contact the laboratory or Accreditation body

Test Report

Report No.TUV(I)/3455/15-16/0081500853

Date: 19 Aug 2015

Name and address of customer : Zenith Industrial Rubber Products Pvt. Ltd. Plot

No. C-15, C-16, C-17, Dombivli Industrial Estate, Phase-I,

Dombivli (East), Dist. Thane

Name of the sample : Silicon Food Grade (White SI 40120 F)

CA No. : **81500853**

Mfg. date/Best before : -

Batch No./ Code no.

Date of sample receipt : 10 Aug 2015

Date(s) of analysis : 17 Aug 2015 -18 Aug 2015

Objectives Of Examination : To test for compliance with US FDA 21.CFR.177.2600 for

Sample drawn by : Customer

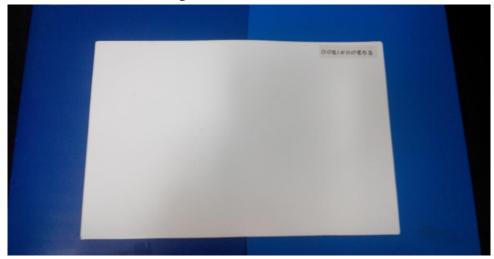
Result Summary :

Test Requested	Conclusion
US FDA 21.CFR.177.2600	PASS

US-FDA test as per 21.CFR.177.2600

Sr. No.	Net Chloroform Soluble Extrctives using Result Unit Limits as per Standard		Test Method				
Total Extra	Total Extractives at Reflux Temperatures for 7 hrs. Using						
1	Distilled Water	2.8	r. 12	20.0			
2	n-Hexane	22.4	mg/inch ²	175.0			
Total Extra	As per USFDA 21.CFR.176.2600						
3	Distilled Water	0.8	ma/inah ²	1.0			
4	n-Hexane	0.8	mg/inch ²	4.0			

Note: Detection Limit for the method is 0.5 mg/inch².



Sample image is authentic only for the original test report

Verified by (Aniket Shaligram) Sr. Laboratory Analyst Authorized by
(V. K. Gupta)

General Manager-Laboratory Operations

- $1. \, Test \, Results \, are \, based \, on \, \& \, related \, only \, to \, the \, particular \, sample(s) \, tested.$
- $2. This \ Report\ cannot \ be\ re-produced, except\ when\ in\ full, without\ the\ written\ permission\ from\ TUV\ India\ Pvt.\ Ltd.,\ Laboratory\ Division.$
- $3. \ This \ Certificate \ reflects our findings at the time and place of testing.$
- 4. Sample(s) will be retained by us for a period of one month for non-perishable items only. Perishable items will be destroyed after completion of tests.
- 5. This Report, in full or in part, shall not be used to make any misleading claims or for any legal purposes.

Date: 19 Aug 2015



DECLARATION

Date: 11.02.2021

This is to put on record that Product manufactured by M/s Zenith Industrial Rubber Products Pvt. Ltd. Is declared that our All Food Grades Product can Compliance with USP 6 STANDARD.

For Zenith Industrial Rubber Products Pvt. Ltd.

Authorized Signatory

Mr. Mohan L. Mahajan

General Manager - Technical