



DECLARATION

TO WHOM IT MAY CONCERN

Date: 15.02.2022

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 EP60130F 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. GR:HL:12520003905 (dated 02-07-2021), 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 + 2nd + 3rd Migration) and EN 1186-3:2002 aqueous food simulants by total immersion method;
- manufactured in accordance to EU regulation 2023/2006;
- compliant to US FDA 21.CFR.177.2600. This is documented with test report nr. GR:HL:2480028584 (dated 07-01-2012), attached to this statement, stating the positive result of the US-FDA test as per 21.CFR.177.2600 (Determination of Amount if Extractives);
- compliant to USP-6 standard.

For Zenith Industrial Rubber Products Pvt. Ltd.

Authorized Signatory
Mr. Mohan L. Mahajan
General Manager - Technical



ULR-TC-62932100029426F

TEST REPORT

Report No. : GR:HL:1252000390

DATE : 02nd July, 2021

ZENITH INDUSTRIAL RUBBER PRODUCTS PVT LTD.

PLOT NO. C-15, C-16, C-17, PHASE – 1, MIDC
DOMBIVLI (EAST), DIST. THANE – 421203
INDIA

CONTACT PERSON: MR. MANISH NANKANI

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION	EPDM FOOD GRADE
LAB IDENTIFIED SAMPLE	RUBBER PART
SAMPLE RECD ON	03/06/2021
TEST PERFORMING DATE	03/06/2021 TO 01/07/2021

SUMMARY OF TEST RESULTS:

TEST REQUESTED	CONCLUSION
NABL ACCREDITED TESTS:	--
EUROPEAN COMMISSION DIRECTIVE 93/11/EEC AND COUNCIL OF EUROPE RESOLUTION AP (2004) 4	--
a) OVERALL MIGRATION	PASS
b) SPECIFIC MIGRATION OF PRIMARY AROMATIC AMINE	PASS
c) SPECIFIC MIGRATION OF NITROSAMINE AND NITROSATABLE SUBSTANCES	PASS

TEST(S) RESULT & METHOD: PLEASE REFER TO NEXT PAGE(S)

Per Pro SGS India Pvt Ltd.

Kapil Patil

Manager-RSL(HL)

Email your Test Report Related Enquiries at Feedback.HLT@sgs.com

JOE No. :2152800137

4747115

Page 1 of 4

Control No.: 1252500528

This document is issued by the Company under its General Conditions of Service printed overleaf or available on request and accessible at http://www.sgs.com/terms_and_conditions.htm and Terms and Conditions for electronic documents www.sgs.com/terms_e-document.htm. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only. This document cannot be reproduced except in full, without prior approval of the Company

SGS India Pvt. Ltd

Consumer and Retail, 226, Udyog Vihar, Phase I, Gurgaon-122016, Haryana, Phone : +91-124-613500 f:91-124- 6776403/404
Regd & Corp. Off: SGS House, 4B, A.S. Marg, Vikhroli (West), Mumbai-400083. Tel: (022) 66408888 Fax : (022) 66408829 www.sgs.com
Member of the SGS Group (SGS SA)



TEST RESULTS:

EUROPEAN COMMISSION DIRECTIVE 93/11/EEC AND COUNCIL OF EUROPE RESOLUTION AP (2004) 4:

a) OVERALL MIGRATION:

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. (1st + 2nd + 3rd Migration);
EN 1186-3:2002 aqueous food simulants by total immersion method;

Simulant Used	Test Condition	Result (mg/dm ²)			Reporting Limit (mg/dm ²)	Permissible Limit (mg/dm ²)
		1 st Migration	2 nd Migration	3 rd Migration		
Distilled Water	40°C for 24 Hours	Not Detected	Not Detected	Not Detected	2.0	10
Stability [^]	--	Yes			--	--
Conclusion	--	Pass			--	--

Tested Item: Rubber Part

Note :-

1. mg/dm² = milligram per square decimeter.
2. °C = degree Celsius.
3. Permissible Limit is according to Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments.
4. Analytical tolerance of aqueous simulants is 2mg/dm² or 12mg/kg.
5. ^ = Stability trend is based on the result of the material from first to third migration test as per described in Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex V for repeated use articles.
6. The compliance is based on the stability trend and 3rd migration result.
7. Test condition & simulant were specified by client.



b) SPECIFIC MIGRATION OF PRIMARY AROMATIC AMINE:

Method: With reference to EN13130-1:2004 and EU JRC guideline EUR 24815 EN 2011. Analysis was performed by LC-MS/MS.

Simulant Used: 3% Acetic Acid (w/v) in aqueous solution

Test Condition: 40°C for 02 Hours (1st Migration + 2nd Migration + 3rd Migration)

Test Item	Result (mg/kg)			Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
	1 st Migration	2 nd Migration	3 rd Migration		
4-Aminobiphenyl	Not Detected	Not Detected	Not Detected	0.002	0.002
Benzidine	Not Detected	Not Detected	Not Detected	0.002	0.002
4-Chloro-o-toluidine	Not Detected	Not Detected	Not Detected	0.002	0.002
2-Naphthylamine	Not Detected	Not Detected	Not Detected	0.002	0.002
o-Aminoazotoluene	Not Detected	Not Detected	Not Detected	0.002	0.002
5-Nitro-o-toluidine	Not Detected	Not Detected	Not Detected	0.002	0.002
4-Chloroaniline	Not Detected	Not Detected	Not Detected	0.002	0.002
4-Methoxy-m-phenylenediamine	Not Detected	Not Detected	Not Detected	0.002	0.002
4,4'-Methylenedianiline	Not Detected	Not Detected	Not Detected	0.002	0.002
3,3'-Dichlorobenzidine	Not Detected	Not Detected	Not Detected	0.002	0.002
3,3'-Dimethoxybenzidine	Not Detected	Not Detected	Not Detected	0.002	0.002
3,3'-Dimethylbenzidine	Not Detected	Not Detected	Not Detected	0.002	0.002
4,4'-Methylenedi-o-toluidine	Not Detected	Not Detected	Not Detected	0.002	0.002
6-Methoxy-m-toluidine	Not Detected	Not Detected	Not Detected	0.002	0.002
4,4'-Methylene-bis-(2-chloro-aniline)	Not Detected	Not Detected	Not Detected	0.002	0.002
4,4'-Oxydianiline	Not Detected	Not Detected	Not Detected	0.002	0.002
4,4'-Thiodianiline	Not Detected	Not Detected	Not Detected	0.002	0.002
o-Toluidine	Not Detected	Not Detected	Not Detected	0.002	0.002
2,4-Toluenediamine	Not Detected	Not Detected	Not Detected	0.002	0.002
2,4,5-Trimethylaniline	Not Detected	Not Detected	Not Detected	0.002	0.002
o-Anisidine	Not Detected	Not Detected	Not Detected	0.002	0.002
4-Amino azobenzene	Not Detected	Not Detected	Not Detected	0.002	0.002
1,3-Phenylenediamine	Not Detected	Not Detected	Not Detected	0.002	0.002
Stability [^]	Yes			--	--
Conclusion	PASS			--	--

Tested Item: Rubber Part

Note :

1. mg/kg = milligram per kilogram of foodstuff in contact with
2. °C = degree Celsius
3. Permissible Limit is according to Commission Regulation (EU) No 10/2011 of 14 January 2011 and its amendment.
4. ^ = Stability trend is based on the result of the material from first to third migration test as per described in Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex V for repeated use articles.
5. The compliance is based on the stability trend and 3rd migration result.
6. Test condition & simulant were specified by the client's.



c) SPECIFIC MIGRATION OF NITROSAMINES AND NITROSATABLE SUBSTANCES:-

Method: With reference to EN 13130-1:2004. Analysis was performed by GC-NPD and GC-MS.

Simulant Used: 3% acetic acid (w/v) in aqueous solution

Test Condition: 40 °C for 02 Hours (1st Migration + 2nd Migration + 3rd Migration)

Test Item	Result (mg/dm ²)			Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
	1 st Migration	2 nd Migration	3 rd Migration		
Nitrosamines	Not Detected	Not Detected	Not Detected	0.01	0.01
Nitrosatable substances	Not Detected	Not Detected	Not Detected	0.02	0.1
Stability [^]	Yes			--	--
Conclusion	Pass			--	--

Tested Item: Rubber Part

Note:

1. mg/kg = milligram per kilogram of foodstuff in contact with
2. Nitrosamines tested: N-nitrosodimethylamine (NDMA), N-nitrosodiethylamine (NDEA), N-nitrosodipropylamine (NDPA), N-nitrosodiisobutylamine (NDiBA), 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) and N-nitrosodiisononylamine (NDiNA).
3. [^] = Stability trend is based on the result of the material from first to third migration test as per described in Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex V for repeated use articles. °C = degree Celsius.
4. Permissible Limit is according to Council of Europe Resolution AP (2004) 4.
5. The compliance is based on the stability trend and 3rd migration result.
6. Above all testing has been performed as per client's request.



***** END OF REPORT*****



TEST REPORT

Report No. : GR:HL:2480028584

DATE : 07th January, 2012

ZENITH INDUSTRIAL RUBBER PRODUCT PVT. LTD.
PLOT NO-C-15,C-16 PHASE 1,MIDC, DOMBIVI
THANE-421203
INDIA
CONTACT PERSON : MS. RANITA

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION EP 60130 W
COLOUR WHITE
STYLE NO. SMOOTH SLAB
COUNTRY OF ORIGIN INDIA
SAMPLE RECEIVING DATE 21/12/2011
TEST PERFORMING DATE 21/12/2011 TO 07/01/2012

TEST(S) REQUESTED FOR COMPLIANCE WITH THE FOOD AND DRUG ADMINISTRATION REGULATIONS FOR DETERMINING THE AMOUNT OF TOTAL EXTRACTIVES FROM RUBBER ARTICLES INTENDED FOR REPEATED USE.

TEST METHOD & RESULT PLS REFER TO NEXT PAGE(S)

CONCLUSION WHEN TEST AS SPECIFIED, THE SUBMITTED SAMPLE(S) COMPLIES WITH THE SPECIFICATIONS FOR THE AMOUNT OF EXTRACTIVES REQUIREMENT FOR RUBBER ARTICLES INTENDED FOR REPEATED USE IN CONTACT WITH AQUEOUS AND FATTY FOODS AS STATED IN US FDA 21 CFR 177. 2600.

Per Pro SGS India Pvt Ltd.

Brijesh Pratap Singh
Sr. Executive
Email your Test Report Related Enquiries at Feedback.HLT@sgs.com

JOE No. : 1148810456

Page 1 of 2

Control No.:2485029012

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/terms> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at www.sgs.com/terms_e-document.htm. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law." Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

SGS India Pvt. Ltd

Consumer Testing Services Laboratory, 250, Udyog Vihar, Phase IV, Gurgaon - 122015, Haryana (India) t: (91-124)60600747 f: (91-124)2399766
Regd. & Corp. Off: SGS House, 4B, A.S. Marg, Vikhroli (West), Mumbai-400083. t: (022) 25798421 to 28 f: (022) 25798431 to 25798435

www.sgs.com

Member of the SGS Group (SGS SA)

TEST REPORT

Report No. : GR:HL:2480028584

DATE : 07th January, 2012

TEST RESULTS:

Test Name – Determination of Amount of extractives

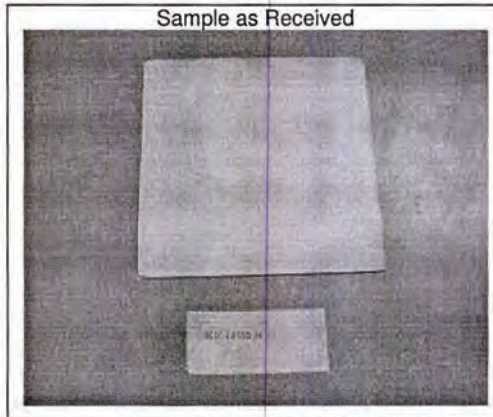
Method: With reference to US FDA 21 CFR 177.2600.

Extractants	Test Condition	Amount of Extractives (mg/inch ²)	Acceptable Limit (mg/inch ²)	Conclusion
		1		
Distilled Water	70°C for 2 hours	<1	<20	Pass
n-Hexane	70°C for 2 hours	<4	<175	Pass

Sample Description : 1. EP 60130 W (White).

- Note :
- 1) mg/inch² = milligram per square inch
 - 2) °C = degrees Celsius
 - 3) Above test is subcontracted to SGS India Pvt. Ltd. Multi Lab, Gurgaon Branch.
 - 4) Extractants & testing condition have been given by client.

Sample as Received



****End of Report****