

TEST REPORT

Report No. : MAN:HL:8480003493

DATE : 03rd July, 2017



RUBTECH MECH INDIA LLP
A48/39A DLF PHASE-1
GURGAON-220012
INDIA
A/C RUBTECH MECHANICALS
CONTACT PERSON : DALJIT SINGH

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

SAMPLE DESCRIPTION BALLS & PLATES
COLOUR WHITE
REFERENCE NO. T 47
SAMPLE RECD ON 07/06/2017
TEST PERFORMING DATE 09/06/2017 TO 03/07/2017

RESULT SUMMARY

TESTS NAME	COMMENTS
1. European Commission Regulation (EU) No 10/2011 and its amendments, and hence Article 3 of European Regulation No. 1935/2004.	--
a) Specific Migration of Neodymium	PASS
b) Specific Migration of Acrylonitrile	PASS
c) Specific Migration of Styrene	PASS
2. European Commission Directive 93/11/EEC – N- Nitrosamines and N-Nitrosatable substance release from elastomer or rubber teats and soothers	PASS
3. NP	SEE RESULT
4. Volatile Organic Compounds (1, 3 Butadiene)	SEE RESULT
5. Bisphenol A Content	SEE RESULT
6. European Commission Directive 93/11/EEC and Council of Europe Resolution AP (2004) 4	---
a) Rubber – Overall Migration	PASS
b) Rubber – Specific Migration of Primary Aromatic Amine	PASS
7. Unwanted material as per LFGB Section 30, 31 (Pb, Cd, Zn)	PASS
8. In accordance with German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB) with its amendment, Section 30 and 31, and Regulation (EC) No 1935/2004.	--
a) Sensory test(DIN 10955)	PASS
9. Polycyclic Aromatic Hydrocarbons (PAH) Content	SEE RESULTS
10. European Regulation (EC) No. 1907/2006 (REACH) Annex XVII and its amendments as specified by client Phthalate Content	PASS
11. US FDA 21 CFR 177.2600 (Rubber Articles) – Determination of Amount of Extractives	PASS

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Per Pro SGS India Pvt Ltd.



Kapil Patil

Asst. Manager

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

1. European Commission Regulation (EU) No 10/2011 and its amendments

a) Specific Migration of Neodymium

Method: Sample preparation in 3% acetic acid (w/v) in aqueous solution at 70°C for 2 hours with reference to EN 13130-1:2004; followed by analysis using Inductively Coupled Argon Plasma Spectrometry (ICP) (1st migration).

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
	1		
Specific Migration of Neodymium	ND	0.01	1
Comment	PASS	--	--

Sample Description :

1. Beige Rubber (Sheet)

Note : 1. mg/kg = milligram per kilogram of foodstuff in contact with

2. °C = degree Celsius

3. ND = Not Detected

b) Specific Migration of Acrylonitrile

Method : Sample preparation in 3% acetic acid (w/v) in aqueous solution at 70°C for 2 hours; followed by analysis using SPME-GC/MS (1st migration).

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
	1		
Specific Migration of Acrylonitrile	ND	0.01	0.01
Comment	PASS	--	--

Sample Description :

1. Beige Rubber (Sheet)

Note : 1. mg/kg = milligram per kilogram of foodstuff in contact with

2. ND = Not Detected

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Remark :

- Compliance is based on the 1st migration result only as per described in Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex V.

c) Specific Migration of Styrene

Method : Sample preparation in 3% acetic acid (w/v) in aqueous solution at 70°C for 2 hours with reference to EN 13130-1:2004; followed by analysis using Liquid Chromatography – Mass Spectrometry (LC-MS) (1st migration).

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Reference Limit (mg/kg)
	1		
Specific Migration of Styrene	ND	5	60
Comment	PASS	--	--

Sample Description :

- Beige Rubber (Sheet)

Note : 1. mg/kg = milligram per kilogram of foodstuff in contact with
2. ND = Not Detected

2. European Commission Directive 93/11/EEC – N-Nitrosamines and N-Nitrosatable substance release from elastomer or rubber teats and soothers

Method : With reference to EN 12868:1999. Analysis was performed by using GC-NPD.

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
	1		
Nitrosamines	ND	0.01	0.01
Nitrosatable substances	ND	0.1	0.1
Comment	PASS	--	--

Sample Description :

- Beige Rubber (Sheet)

Note : 1. 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 (NMPHA), N-nitroso-N-ethyl-N-phenylamine (NEPhA) and N-nitrosodiisononylamine (NDiNA).

- mg/kg = milligram per kilogram
- ND = Not Detected
- Above all testing has been subcontracted to SGS Overseas lab.

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TEST NAME	METHOD	RESULT	DETECTION LIMIT
3.NP	SOLVENT EXTRACTION/ANALYSIS BY LC-MS/GCMS	ND	10 mg/kg
4. VOLATILE ORGANIC COMPOUNDS (1, 3 Butadiene)	IN HOUSE METHOD, ANALYSIS BY GC MS HEAD SPACE	ND	1 mg/kg
5.BISPHENOL A CONTENT	SOLVENT EXTRACTION/ANALYSIS BY LC-MS/GCMS	ND	1 mg/kg

Sample Description : BALLS & PLATES

Note:

1. Detection Limit = 1 mg/kg, ND=Not Detected
2. mg/kg = milligram per kilograms
3. Testing has been performed as per applicant's request.
4. Testing has been subcontracted to SGS approved lab.

6) Commission Directive 93/11/EEC and Council of Europe Resolution AP (2004) 4

a) Rubber – 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

Simulant Used	Test Condition	Result(mg/dm ²)	Reporting Limit(mg/dm ²)	Permissible Limit(mg/dm ²)
3% Acetic Acid	02 Hours at 70°C	1 < 2	3.0	10
Comment	--	PASS		--

Sample Description : BALL & PLATES

- Note:
1. mg/dm² = milligram per square decimeter.
 2. °C = degree Celsius, < = less than
 3. Test condition & simulant were specified by client
 4. Permissible Limit is according to Council of Europe Resolution AP (2004) 4.
 5. Testing has been performed as per the Client's request

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b) Rubber – Specific migration of Primary Aromatic Amine

Method: With reference to EN 13130-1:2004 and BfR Recommendation XXI. Analysis was performed by UV-vis Spectrophotometer.

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

Test Condition: 70 °C For 02 Hours (1st Migration)

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
	1		
Specific migration of Primary Aromatic Amine	<0.01	0.01	0.01
Comment	PASS	--	--

Sample Description: BALLS & PLATES

- Note: 1. mg/kg = milligram per kilogram of foodstuff in contact with
- 2. °C = degree Celsius
- 3. ND = Not Detected
- 4. Testing condition and simulant were specified by client.
- 5. Permissible Limit is according to Council of Europe Resolution AP (2004) 4.

7. Unwanted material as per LFGB Section 30, 31 (Pb, Cd, Zn)

a)

Test method: Acid digestion followed by AAS ICP-OES

TESTED ELEMENT	TEST RESULT (mg/kg)	REPORTING LIMIT (mg/kg)	PERMISSIBLE LIMIT (mg/kg)
Lead (Pb)	ND	2	30 (cat 1,2,3) / 10 (special cat)
Cadmium (Cd)	ND	2	Absent
Zinc (Zn)	280.22	100	30000 (cat 1,2,3) / 10000 (special cat)
Conclusion	Pass	-	-

Sample Description : BALLS & PLATES

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8. Sensorial examination odour and taste test

Test Requested : In accordance with German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB) with its amendment, Section 30 and 31, and Regulation (EC) No 1935/2004.

For material: Sensorial examination of odour and taste

Test Method : With reference to DIN 10955:2004.

Test media: Water

No.of panelist: 6

Test Item(s)	Limit	001
Test time (hr(s))	-	02
Temperature(°)	-	70
Sensorial examination odour (Point scale)	2.5	0
Sensorial examination taste (Point scale)	2.5	0
Conclusion		PASS

Sample Description : BALLS & PLATES

Notes :

Scale evaluation:

- 0 – no perceptible difference
- 1 – just perceptible difference
- 2 – slight difference
- 3 – marked difference
- 4 – strong difference

Note:

1. Testing has been performed as per client's request.
2. Permissible limit is according to LFGB with its amendment, Section 30 and 31, and Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004

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9. POLYCYCLIC AROMATIC HYDROCARBON (PAH):

Test Method: With reference to AFPS GS 2014:01 PAK. Analysis was conducted by Gas Chromatography- Mass Spectrometry.

<u>Test Item</u>	<u>CAS Number</u>	<u>RESULTS (mg/kg)</u>	<u>Reporting Limit (mg/kg)</u>
		<u>Sample-1</u>	
Naphthalene (NAP)	91-20-3	ND	0.2 mg/kg
Acenaphthylene (ANY)	208-96-8	ND	
Acenaphthene (ANA)	83-32-9	ND	
Fluorene (FLU)	86-73-7	ND	
Phenanthrene (PHE)	85-01-8	ND	
Anthracene (ANT)	120-12-7	ND	
Fluoranthene (FLT)	206-44-0	ND	
Pyrene (PYR)	129-00-0	ND	
Benzo(a)anthracene (BaA)	56-55-3	ND	
Chrysene (CHR)	218-01-9	ND	
Benzo(b)fluoranthene (BbF)	205-99-2	ND	
Benzo(j)fluoranthene(BjF)	205-82-3	ND	
Benzo(k)fluoranthene (BkF)	207-08-9	ND	
Benzo(a)pyrene (BaP)	50-32-8	ND	
Indeno(1,2,3-c,d)pyrene (IPY)	193-39-5	ND	
Dibenzo(a,h)anthracene (DBA)	53-70-3	ND	
Benzo(g,h,i)perylene (BPE)	191-24-2	ND	
Benzo(e)pyrene(BeP)	192-97-2	ND	
Sum of 18 PAHs	--	ND	
Comment	--	See GS PAH Requirement	

Tested Sample Description: BALLS & PLATES (ON BALL).

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AfPS (German commission for Product Safety) : GS PAHs requirements

Polycyclic Aromatic Hydrocarbon	Category 1	Category 2		Category 3	
	Materials intended to be placed in the mouth or toys with intended prolonged skin contact (> 30 seconds) (mg/kg)	Materials not falling under Category 1, with foreseeable skin contact longer than 30seconds (long term skin or frequent contact)		Materials not falling under Category 1 or 2, with foreseeable skin contact less than 30 seconds (short-term skin contact)	
		Toys (TSD) (mg/kg)	Other products according to ProdSG (mg/kg)	Toys (TSD) (mg/kg)	Other products according to ProdSG (mg/kg)
Benzo[a]pyrene	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Benzo[e]pyrene	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Benzo[a]anthracene	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Dibenzo[a,h]anthracene	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Benzo[b]fluoranthene	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Benzo[j]fluoranthene	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Benzo[k]fluoranthene	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Chrysene	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Benzo[g,h,i]perylene	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Ideno[1,2,3-cd]pyrene	< 0.2	< 0.2	< 0.5	< 0.5	< 1
Acenaphthylene	< 1 (sum)	< 5 (sum)	< 10 (sum)	< 20 (sum)	< 50 (sum)
Acenaphthene					
Anthracene					
Fluorene					
Fluoranthene					
Phenanthrene					
Pyrene					
Naphthalene	< 1	< 2	< 2	< 10	< 10
Sum of 18 PAHs	< 1	< 5	< 10	< 20	< 50

Note :

1. mg/kg = milligram per kilogram
2. ND = Not Detected
3. Testing has been subcontracted to SGS approved lab.
4. Testing has been performed as per Client's request.

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10. PHTHALATES

European Regulation (EC) No. 1907/2006 (REACH) Annex XVII and its amendments

Test Method: With reference to CPSC-CH-C 1001-09.3 - Analysis was conducted by GC-MS.

Test item	Results (%)	Permissible Limit
	1	
Dibutyl Phthalate (DBP)	ND	<0.1%
Benzylbutyl Phthalate (BBP)	ND	<0.1%
Bis-(2-ethylhexyl) Phthalate (DEHP)	ND	<0.1%
Diisononyl Phthalate (DINP)	ND	<0.1%
Di-n-octyl Phthalate (DNOP)	ND	<0.1%
Diisodecyl Phthalate (DIDP)	ND	<0.1%
Conclusion	PASS	--

Sample Description : BALLS & PLATES (ON BALL).

Note:

- 1) ND = not detected
- 2) < = Less than, > = Greater than
- 3) % = percentage by weight
- 4) Detection limit: 100 ppm (0.01%)
- 5) Testing has been performed as per applicant's request.

Remark:

Permissible limit specified by entries 51 and 52 of regulation (EC) No 552/2009 amending Annex XVII of REACH Regulation (EC) No 1907/2006 (previously restricted under Directive 2005/84/EC).

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Test Results: 11.

US FDA 21 CFR 177.2600 (Rubber Articles) – Determination of Amount of Extractives

Method : With reference to US FDA 21 CFR 177.2600.

For use in contact with aqueous food:

Extractants	Test Condition	Result (mg/inch ²)	Reporting Limit (mg/inch ²)	Permissible Limit (mg/inch ²)
Distilled Water	Reflux temperature for 7 hours	<0.1	0.1	20
	Succeeding 2 hours of extraction	<0.1	0.1	1
Comment	--	PASS	--	--

Sample Description : BALLS & PLATES

For use in contact with fatty food:

Extractants	Test Condition	Result (mg/inch ²)	Reporting Limit (mg/inch ²)	Permissible Limit (mg/inch ²)
n-Hexane	Reflux temperature for 7 hours	<0.1	0.1	175
	Succeeding 2 hours of extraction	<0.1	0.1	4
Comment	--	PASS	--	--

Sample Description : BALLS & PLATES

- Note : 1. mg/inch² = milligram per square inch
 2. Test Condition has been provided by client.

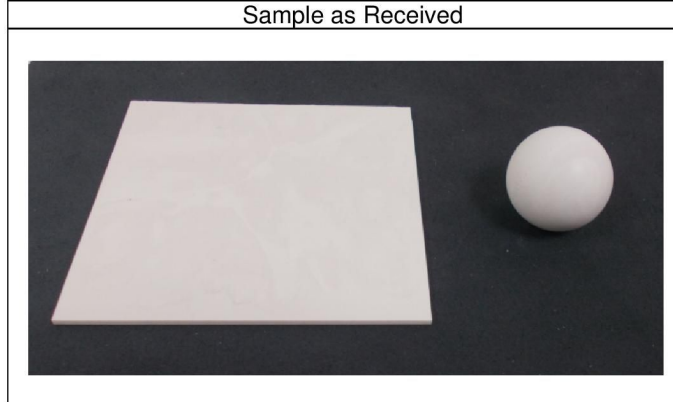
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Sample as Received



*****End of Report*****

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