



Test Report No. 70.400.24.1906.01-00.01
Rev. 00
Dated 2024-09-19

Applicant: LEFOO INDUSTRIAL CO.,LTD

Address: NO.118 Changda Road, Linping Street, Linping District, Hangzhou City, Zhejiang Province

Sample Description: Micro Pumps

Model No.: LFP

Sample Received Date: 2024-07-29

Test Period: From 2024-07-29 to 2024-09-12

Purpose of examination: As specified by client, to test as regulated by the Regulation (EC) No.1935/2004

Test Result: Refer to following page(s)

Remark: 1. The result relates only to the items tested.
2. The testing approach, the testing methods, and the reported results in this report demonstrate compliance or non-compliance to the client's requirements which were mutually agreed at the contract review and stipulated in the quotation. The testing approach, the testing methods, and the reported results may not or only partially fulfil the associated requirements of the applicable regulations.

TÜV SÜD Certification and Testing (China) Co., Ltd. Shanghai Branch
TÜV SÜD Group

Prepared by:

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Reviewed by:

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Designated Reviewer

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Disclaimer Measurement Uncertainty: Unless otherwise agreed upon, pass or fail verdicts are given based on the measured values without consideration of measurement uncertainties. Please note, every test method has a measurement uncertainty which has been evaluated by the laboratory according to ISO IEC 17025 requirements. By taking measurement uncertainties into account it might happen that measured values can neither be assessed as pass or fail.

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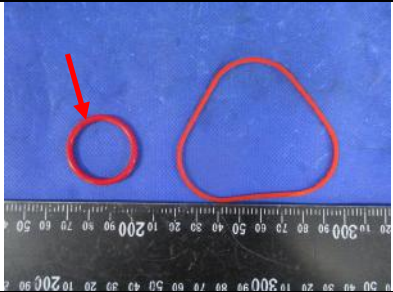



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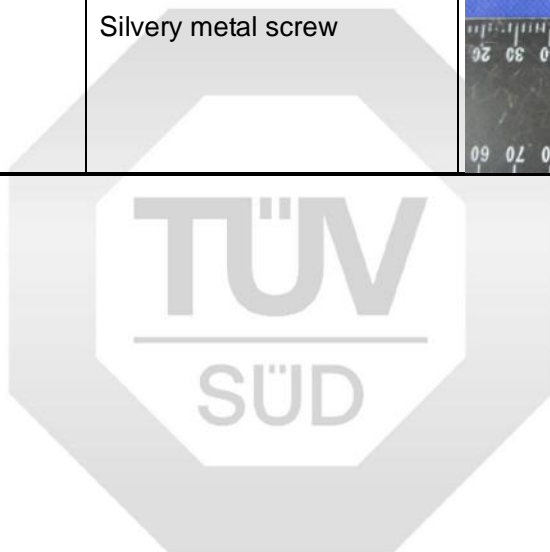
SUMMARY OF TEST RESULTS

Test Requested	Conclusion	Remarks
For material: Plastics Test for compliance with regulation (EU) No. 10/2011 and its amendments (EU) No. 2016/1416, (EU) No. 2017/752, (EU) No. 2018/79, (EU) No. 284/2011, (EU) No. 2018/213, (EU) No. 2020/1245, (EU) No. 2023/1442. 1. Overall Migration 2. Specific Migration of 19 Heavy Metals 3. Specific Migration of Primary Aromatic Amine 4. Specific Migration of Hexamethylenediamine	PASS	
For material: Silicone Test for compliance with Resolution AP (2004)5. 5. Overall migration	PASS	
For material: Rubber Test for compliance with Resolution AP (2004)4, (EU) No. 10/2011 and its amendments (EU) No. 2023/1442. 6. Overall migration 7. Specific Migration of Primary Aromatic Amine 8. Specific Migration of N-nitrosamines and N-nitrosatable substances 9. Total 1,3-Butadiene content 10. Specific Migration of 1,3-Butadiene	PASS	
For material: Metal and Metal alloy Test for compliance with European Directorate for the Quality of Medicines & Healthcare Technical guide Resolution CM/Res(2020)9. 11. Specific Migration of 22 Heavy Metals	PASS	
Sensory test 12. Sensory test with reference to DIN 10955: 2024	PASS	

1. TESTED SUBJECT DESCRIPTION

Sample Number	Item Name	Tested Material Description	Photo
001	silicone	Red soft ring	
002	EPDM	Black soft plastic block	
003	PA66	Black plastic block	
004	NBR	Black soft plastic block	

Sample Number	Item Name	Tested Material Description	Photo
005	TPV	Beige soft plastic block	
006	SUS 304	Silvery metal screw	





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2. TEST RESULT
2.1. OVERALL MIGRATION TEST FOR PLASTICS

Test method: As specified in Regulation (EU) No. 10/2011 and its amendments; with reference to EN 1186-1: 2002, EN 1186-2: 2022, EN 1186-3: 2022, EN 1186-13: 2002.

Surface area to Volume ratio: 1.2dm² : 120ml

Simulant Used	Test Condition	Result [mg/dm ²]			Requirement [mg/dm ²]
		Sample 003			
		1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & 3 rd migration limit
20% Ethanol	40 °C for 10 days	4.8	< 3.0	< 3.0	≤ 10

Note:

- “mg/dm²” denotes milligram per square decimeter.
- The specification was quoted from regulation (EU) No. 10/2011 and its amendment (EU) No. 2020/1245.



2.2. SPECIFIC MIGRATION OF 19 HEAVY METALS TEST FOR PLASTICS

Test method: As specified in Regulation (EU) No. 10/2011 and its amendments; the sample(s) were migrated with food simulant, followed by Inductively Coupled Plasma Mass Spectrometry(ICP-MS) analysis.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.

Surface area to Volume ratio: 1.2dm² : 200ml

Test Item		Result [mg/kg]			Requirement [mg/kg]
		Sample 003			
		1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & 3 rd migration limit
Barium	(Ba)	<0.10	<0.10	<0.10	≤ 1
Cobalt	(Co)	<0.05	<0.05	<0.05	≤ 0.05
Copper	(Cu)	<0.10	<0.10	<0.10	≤ 5
Iron	(Fe)	<0.10	<0.10	<0.10	≤ 48
Lithium	(Li)	<0.06	<0.06	<0.06	≤ 0.6
Manganese	(Mn)	<0.02	<0.02	<0.02	≤ 0.6
Zinc	(Zn)	<0.10	<0.10	<0.10	≤ 5
Aluminium	(Al)	<0.10	<0.10	<0.10	≤ 1
Nickel	(Ni)	<0.02	<0.02	<0.02	≤ 0.02
Antimony	(Sb)	<0.01	<0.01	<0.01	≤ 0.04
Arsenic	(As)	<0.01	<0.01	<0.01	Not Detected (< 0.01)
Cadmium	(Cd)	<0.002	<0.002	<0.002	Not Detected (< 0.002)
Chromium	(Cr)	<0.01	<0.01	<0.01	Not Detected (< 0.01)
Lead	(Pb)	<0.01	<0.01	<0.01	Not Detected (< 0.01)
Mercury	(Hg)	<0.01	<0.01	<0.01	Not Detected (< 0.01)
Lanthanum	(La)	<0.01	<0.01	<0.01	Sum ≤ 0.05
Europium	(Eu)	<0.01	<0.01	<0.01	
Gadolinium	(Gd)	<0.01	<0.01	<0.01	
Terbium	(Tb)	<0.01	<0.01	<0.01	

Note:

- “mg/kg” denotes milligram per kilogram foodstuff.
- The specification was quoted from regulation (EU) No. 10/2011 and its amendment (EU) No. 2020/1245.

2.3. SPECIFIC MIGRATION OF PRIMARY AROMATIC AMINE TEST FOR PLASTICS

Test method: As specified in Regulation (EU) No. 10/2011 and its amendments; the sample(s) were migrated with food stimulant, followed by Ultraviolet-visible Spectrophotometer (UV-Vis) analysis.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.

Surface area to Volume ratio: 1.2dm² : 200ml

Test Item	Result [mg/kg]			Requirement [mg/kg]
	Sample 003			
	1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & each migration limit
Migration of Primary Aromatic Amine	< 0.01	< 0.01	< 0.01	Not Detected (< 0.01)

Test method: As specified in Regulation (EU) No. 10/2011 and its amendments; the sample(s) were migrated with food stimulant, followed by Liquid Chromatography with Tandem Mass Spectrometry Detection (LC-MS/MS) analysis.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.

Surface area to Volume ratio: 1.2dm² : 200ml

No.	Test Item	CAS No.	Result [mg/kg]			Requirement [mg/kg]
			Sample 003			
			1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & each migration limit
1	biphenyl-4-ylamine 4-aminobiphenyl xenylamine	92-67-1	<0.002	<0.002	<0.002	< 0.002
2	Benzidine	92-87-5	<0.002	<0.002	<0.002	< 0.002
3	4-chloro-o-toluidine	95-69-2	<0.002	<0.002	<0.002	< 0.002
4	2-naphthylamine	91-59-8	<0.002	<0.002	<0.002	< 0.002
5	o-aminoazotoluene 4-amino-2',3'-dimethylazobenzene 4-o-tolylazo-o-toluidine	97-56-3	<0.002	<0.002	<0.002	< 0.002
6	5-nitro-o-toluidine	99-55-8	<0.002	<0.002	<0.002	< 0.002
7	4-chloroaniline	106-47-8	<0.002	<0.002	<0.002	< 0.002
8	4-methoxy-m-phenylenediamine	615-05-4	<0.002	<0.002	<0.002	< 0.002
9	4,4'-methylenedianiline 4,4'-diaminodiphenylmethane	101-77-9	<0.002	<0.002	<0.002	< 0.002
10	3,3'-dichlorobenzidine 3,3'-dichlorobiphenyl-4,4'-ylenediamine	91-94-1	<0.002	<0.002	<0.002	< 0.002
11	3,3'-dimethoxybenzidine o-dianisidine	119-90-4	<0.002	<0.002	<0.002	< 0.002
12	3,3'-dimethylbenzidine 4,4'-bi-o-toluidine	119-93-7	<0.002	<0.002	<0.002	< 0.002
13	4,4'-methylenedi-o-toluidine	838-88-0	<0.002	<0.002	<0.002	< 0.002

No.	Test Item	CAS No.	Result [mg/kg]			Requirement [mg/kg]
			Sample 003			
			1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & each migration limit
14	6-methoxy-m-toluidine p-cresidine	120-71-8	<0.002	<0.002	<0.002	< 0.002
15	4,4'-methylene-bis-(2-chloro-aniline) 2,2'-dichloro-4,4'-methylene-dianiline	101-14-4	<0.002	<0.002	<0.002	< 0.002
16	4,4'-oxydianiline	101-80-4	<0.002	<0.002	<0.002	< 0.002
17	4,4'-thiodianiline	139-65-1	<0.002	<0.002	<0.002	< 0.002
18	o-toluidine 2-aminotoluene	95-53-4	<0.002	<0.002	<0.002	< 0.002
19	4-methyl-m-phenylenediamine	95-80-7	<0.002	<0.002	<0.002	< 0.002
20	2,4,5-trimethylaniline	137-17-7	<0.002	<0.002	<0.002	< 0.002
21	o-anisidine 2-methoxyaniline	90-04-0	<0.002	<0.002	<0.002	< 0.002
22	4-amino azobenzene	60-09-3	<0.002	<0.002	<0.002	< 0.002
23	1,5- Diaminenaphthalene	2243-62-1	<0.002	<0.002	<0.002	< 0.002
24	Aniline (ANL)	62-53-3	<0.002	<0.002	<0.002	< 0.002
25	2,4-Dimethylaniline (2,4-DMA)	95-68-1	<0.002	<0.002	<0.002	< 0.002
26	2,6-Dimethylaniline (2,6-DMA)	87-62-7	<0.002	<0.002	<0.002	< 0.002
27	m-Phenylenediamine (m-PDA)	108-45-2	<0.002	<0.002	<0.002	< 0.002
28	p-Phenylenediamine (p-PDA)	106-50-3	<0.002	<0.002	<0.002	< 0.002
29	2,6-Toluenediamine (2,6-TDA)	823-40-5	<0.002	<0.002	<0.002	< 0.002

Note:

- “mg/kg” denotes milligram per kilogram foodstuff.
- The specification was quoted from regulation (EU) No. 10/2011 and its amendment (EU) No. 2020/1245.

2.4. SPECIFIC MIGRATION OF HEXAMETHYLENEDIAMINE TEST FOR PLASTICS

Test method: As specified in Regulation (EU) No. 10/2011 and its amendments; the sample(s) were migrated with food simulant, followed by Gas Chromatography/Mass Spectrometry (GC-MS) analysis.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.

Surface area to Volume ratio: 1.2dm² : 200ml

Test Item	CAS No.	Result [mg/kg]			Requirement [mg/kg]
		Sample 003			
		1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & 3 rd migration limit
Migration of Hexamethylenediamine	124-09-4	< 1.0	< 1.0	< 1.0	≤ 2.4

Note:

- “mg/kg” denotes milligram per kilogram foodstuff.
- The specification was quoted from regulation (EU) No. 10/2011 and its amendment (EU) No. 2020/1245.

2.5. OVERALL MIGRATION TEST FOR SILICONE

Test method: As specified in Resolution AP (2004)5; with reference to EN 1186-1: 2002, EN 1186-2: 2022, EN 1186-3: 2022, EN 1186-13: 2002.

Surface area to Volume ratio: 1.01dm² : 101ml

Simulant Used	Test Condition	Result [mg/dm ²]	Requirement [mg/dm ²]
		Sample 001	
20% Ethanol	40 °C for 10 days	< 3.0	≤ 10

Note:

- “mg/dm²” denotes milligram per square decimeter.
- The specification was quoted from Resolution AP (2004)5.

2.6. OVERALL MIGRATION TEST FOR RUBBER

Test method: As specified in Regulation (EU) No. 10/2011 and its amendments; with reference to EN 1186-1: 2002, EN 1186-2: 2022, EN 1186-3: 2022, EN 1186-13: 2002.

Surface area to Volume ratio: 1.1dm² : 110ml

Simulant Used	Test Condition	Result [mg/dm ²]			Requirement [mg/dm ²]
		Sample 002			
		1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & 3 rd migration limit
20% Ethanol	40 °C for 10 days	4.64	< 3.0	< 3.0	≤ 10

Surface area to Volume ratio: 1.04dm² : 104ml

Simulant Used	Test Condition	Result [mg/dm ²]			Requirement [mg/dm ²]
		Sample 004			
		1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & 3 rd migration limit
20% Ethanol	40 °C for 10 days	< 3.0	< 3.0	< 3.0	≤ 10

Surface area to Volume ratio: 1.04dm² : 104ml

Simulant Used	Test Condition	Result [mg/dm ²]			Requirement [mg/dm ²]
		Sample 005			
		1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & 3 rd migration limit
20% Ethanol	40 °C for 10 days	< 3.0	< 3.0	< 3.0	≤ 10

Note:

- “mg/dm²” denotes milligram per square decimeter.
- The specification was quoted from regulation (EU) No. 10/2011 and its amendment (EU) No. 2020/1245.

2.7. SPECIFIC MIGRATION OF PRIMARY AROMATIC AMINE TEST FOR RUBBER

Test method: As specified in Regulation (EU) No. 10/2011 and its amendments; the sample(s) were migrated with food stimulant, followed by Ultraviolet-visible Spectrophotometer (UV-Vis) analysis.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.

Surface area to Volume ratio: 0.686dm² : 114ml

Test Item	Result [mg/kg]			Requirement [mg/kg]
	Sample 002			
	1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & each migration limit
Migration of Primary Aromatic Amine	< 0.01	< 0.01	< 0.01	Not Detected (< 0.01)

Test method: As specified in Regulation (EU) No. 10/2011 and its amendments; the sample(s) were migrated with food stimulant, followed by Liquid Chromatography with Tandem Mass Spectrometry Detection (LC-MS/MS) analysis.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.

Surface area to Volume ratio: 0.686dm² : 114ml

No.	Test Item	CAS No.	Result [mg/kg]			Requirement [mg/kg]
			Sample 002			
			1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & each migration limit
1	biphenyl-4-ylamine 4-aminobiphenyl xenylamine	92-67-1	<0.002	<0.002	<0.002	< 0.002
2	Benzidine	92-87-5	<0.002	<0.002	<0.002	< 0.002
3	4-chloro-o-toluidine	95-69-2	<0.002	<0.002	<0.002	< 0.002
4	2-naphthylamine	91-59-8	<0.002	<0.002	<0.002	< 0.002
5	o-aminoazotoluene 4-amino-2',3'-dimethylazobenzene 4-o-tolylazo-o-toluidine	97-56-3	<0.002	<0.002	<0.002	< 0.002
6	5-nitro-o-toluidine	99-55-8	<0.002	<0.002	<0.002	< 0.002
7	4-chloroaniline	106-47-8	<0.002	<0.002	<0.002	< 0.002
8	4-methoxy-m-phenylenediamine	615-05-4	<0.002	<0.002	<0.002	< 0.002
9	4,4'-methylenedianiline 4,4'-diaminodiphenylmethane	101-77-9	<0.002	<0.002	<0.002	< 0.002
10	3,3'-dichlorobenzidine 3,3'-dichlorobiphenyl-4,4'-ylenediamine	91-94-1	<0.002	<0.002	<0.002	< 0.002
11	3,3'-dimethoxybenzidine o-dianisidine	119-90-4	<0.002	<0.002	<0.002	< 0.002
12	3,3'-dimethylbenzidine 4,4'-bi-o-toluidine	119-93-7	<0.002	<0.002	<0.002	< 0.002
13	4,4'-methylenedi-o-toluidine	838-88-0	<0.002	<0.002	<0.002	< 0.002

No.	Test Item	CAS No.	Result [mg/kg]			Requirement [mg/kg]
			Sample 002			
			1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & each migration limit
14	6-methoxy-m-toluidine p-cresidine	120-71-8	<0.002	<0.002	<0.002	< 0.002
15	4,4'-methylene-bis-(2-chloro-aniline) 2,2'-dichloro-4,4'-methylene-dianiline	101-14-4	<0.002	<0.002	<0.002	< 0.002
16	4,4'-oxydianiline	101-80-4	<0.002	<0.002	<0.002	< 0.002
17	4,4'-thiodianiline	139-65-1	<0.002	<0.002	<0.002	< 0.002
18	o-toluidine 2-aminotoluene	95-53-4	<0.002	<0.002	<0.002	< 0.002
19	4-methyl-m-phenylenediamine	95-80-7	<0.002	<0.002	<0.002	< 0.002
20	2,4,5-trimethylaniline	137-17-7	<0.002	<0.002	<0.002	< 0.002
21	o-anisidine 2-methoxyaniline	90-04-0	<0.002	<0.002	<0.002	< 0.002
22	4-amino azobenzene	60-09-3	<0.002	<0.002	<0.002	< 0.002
23	1,5- Diaminenaphthalene	2243-62-1	<0.002	<0.002	<0.002	< 0.002
24	Aniline (ANL)	62-53-3	<0.002	<0.002	<0.002	< 0.002
25	2,4-Dimethylaniline (2,4-DMA)	95-68-1	<0.002	<0.002	<0.002	< 0.002
26	2,6-Dimethylaniline (2,6-DMA)	87-62-7	<0.002	<0.002	<0.002	< 0.002
27	m-Phenylenediamine (m-PDA)	108-45-2	<0.002	<0.002	<0.002	< 0.002
28	p-Phenylenediamine (p-PDA)	106-50-3	<0.002	<0.002	<0.002	< 0.002
29	2,6-Toluenediamine (2,6-TDA)	823-40-5	<0.002	<0.002	<0.002	< 0.002

Note:

- “mg/kg” denotes milligram per kilogram foodstuff.
- The specification was quoted from regulation (EU) No. 10/2011 and its amendment (EU) No. 2020/1245.

Test method: As specified in Regulation (EU) No. 10/2011 and its amendments; the sample(s) were migrated with food stimulant, followed by Ultraviolet-visible Spectrophotometer (UV-Vis) analysis.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.

Surface area to Volume ratio: 0.631dm² : 105ml

Test Item	Result [mg/kg]			Requirement [mg/kg]
	Sample 004			
	1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & each migration limit
Migration of Primary Aromatic Amine	< 0.01	< 0.01	< 0.01	Not Detected (< 0.01)

Test method: As specified in Regulation (EU) No. 10/2011 and its amendments; the sample(s) were migrated with food stimulant, followed by Liquid Chromatography with Tandem Mass Spectrometry Detection (LC-MS/MS) analysis.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.

Surface area to Volume ratio: 0.631dm² : 105ml

No.	Test Item	CAS No.	Result [mg/kg]			Requirement [mg/kg]
			Sample 004			
			1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & each migration limit
1	biphenyl-4-ylamine 4-aminobiphenyl xenylamine	92-67-1	<0.002	<0.002	<0.002	< 0.002
2	Benzidine	92-87-5	<0.002	<0.002	<0.002	< 0.002
3	4-chloro-o-toluidine	95-69-2	<0.002	<0.002	<0.002	< 0.002
4	2-naphthylamine	91-59-8	<0.002	<0.002	<0.002	< 0.002
5	o-aminoazotoluene 4-amino-2',3'-dimethylazobenzene 4-o-tolylazo-o-toluidine	97-56-3	<0.002	<0.002	<0.002	< 0.002
6	5-nitro-o-toluidine	99-55-8	<0.002	<0.002	<0.002	< 0.002
7	4-chloroaniline	106-47-8	<0.002	<0.002	<0.002	< 0.002
8	4-methoxy-m-phenylenediamine	615-05-4	<0.002	<0.002	<0.002	< 0.002
9	4,4'-methylenedianiline 4,4'-diaminodiphenylmethane	101-77-9	<0.002	<0.002	<0.002	< 0.002
10	3,3'-dichlorobenzidine 3,3'-dichlorobiphenyl-4,4'-ylenediamine	91-94-1	<0.002	<0.002	<0.002	< 0.002
11	3,3'-dimethoxybenzidine o-dianisidine	119-90-4	<0.002	<0.002	<0.002	< 0.002
12	3,3'-dimethylbenzidine 4,4'-bi-o-toluidine	119-93-7	<0.002	<0.002	<0.002	< 0.002
13	4,4'-methylenedi-o-toluidine	838-88-0	<0.002	<0.002	<0.002	< 0.002

No.	Test Item	CAS No.	Result [mg/kg]			Requirement [mg/kg]
			Sample 004			
			1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & each migration limit
14	6-methoxy-m-toluidine p-cresidine	120-71-8	<0.002	<0.002	<0.002	< 0.002
15	4,4'-methylene-bis-(2-chloro-aniline) 2,2'-dichloro-4,4'-methylene-dianiline	101-14-4	<0.002	<0.002	<0.002	< 0.002
16	4,4'-oxydianiline	101-80-4	<0.002	<0.002	<0.002	< 0.002
17	4,4'-thiodianiline	139-65-1	<0.002	<0.002	<0.002	< 0.002
18	o-toluidine 2-aminotoluene	95-53-4	<0.002	<0.002	<0.002	< 0.002
19	4-methyl-m-phenylenediamine	95-80-7	<0.002	<0.002	<0.002	< 0.002
20	2,4,5-trimethylaniline	137-17-7	<0.002	<0.002	<0.002	< 0.002
21	o-anisidine 2-methoxyaniline	90-04-0	<0.002	<0.002	<0.002	< 0.002
22	4-amino azobenzene	60-09-3	<0.002	<0.002	<0.002	< 0.002
23	1,5- Diaminenaphthalene	2243-62-1	<0.002	<0.002	<0.002	< 0.002
24	Aniline (ANL)	62-53-3	<0.002	<0.002	<0.002	< 0.002
25	2,4-Dimethylaniline (2,4-DMA)	95-68-1	<0.002	<0.002	<0.002	< 0.002
26	2,6-Dimethylaniline (2,6-DMA)	87-62-7	<0.002	<0.002	<0.002	< 0.002
27	m-Phenylenediamine (m-PDA)	108-45-2	<0.002	<0.002	<0.002	< 0.002
28	p-Phenylenediamine (p-PDA)	106-50-3	<0.002	<0.002	<0.002	< 0.002
29	2,6-Toluenediamine (2,6-TDA)	823-40-5	<0.002	<0.002	<0.002	< 0.002

Note:

- “mg/kg” denotes milligram per kilogram foodstuff.
- The specification was quoted from regulation (EU) No. 10/2011 and its amendment (EU) No. 2020/1245.

Test method: As specified in Regulation (EU) No. 10/2011 and its amendments; the sample(s) were migrated with food stimulant, followed by Ultraviolet-visible Spectrophotometer (UV-Vis) analysis.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.

Surface area to Volume ratio: 1.04dm² : 173ml

Test Item	Result [mg/kg]			Requirement [mg/kg]
	Sample 005			
	1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & each migration limit
Migration of Primary Aromatic Amine	< 0.01	< 0.01	< 0.01	Not Detected (< 0.01)

Test method: As specified in Regulation (EU) No. 10/2011 and its amendments; the sample(s) were migrated with food stimulant, followed by Liquid Chromatography with Tandem Mass Spectrometry Detection (LC-MS/MS) analysis.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.

Surface area to Volume ratio: 1.04dm² : 173ml

No.	Test Item	CAS No.	Result [mg/kg]			Requirement [mg/kg]
			Sample 005			
			1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & each migration limit
1	biphenyl-4-ylamine 4-aminobiphenyl xenylamine	92-67-1	<0.002	<0.002	<0.002	< 0.002
2	Benzidine	92-87-5	<0.002	<0.002	<0.002	< 0.002
3	4-chloro-o-toluidine	95-69-2	<0.002	<0.002	<0.002	< 0.002
4	2-naphthylamine	91-59-8	<0.002	<0.002	<0.002	< 0.002
5	o-aminoazotoluene 4-amino-2',3'-dimethylazobenzene 4-o-tolylazo-o-toluidine	97-56-3	<0.002	<0.002	<0.002	< 0.002
6	5-nitro-o-toluidine	99-55-8	<0.002	<0.002	<0.002	< 0.002
7	4-chloroaniline	106-47-8	<0.002	<0.002	<0.002	< 0.002
8	4-methoxy-m-phenylenediamine	615-05-4	<0.002	<0.002	<0.002	< 0.002
9	4,4'-methylenedianiline 4,4'-diaminodiphenylmethane	101-77-9	<0.002	<0.002	<0.002	< 0.002
10	3,3'-dichlorobenzidine 3,3'-dichlorobiphenyl-4,4'-ylenediamine	91-94-1	<0.002	<0.002	<0.002	< 0.002
11	3,3'-dimethoxybenzidine o-dianisidine	119-90-4	<0.002	<0.002	<0.002	< 0.002
12	3,3'-dimethylbenzidine 4,4'-bi-o-toluidine	119-93-7	<0.002	<0.002	<0.002	< 0.002
13	4,4'-methylenedi-o-toluidine	838-88-0	<0.002	<0.002	<0.002	< 0.002

No.	Test Item	CAS No.	Result [mg/kg]			Requirement [mg/kg]
			Sample 005			
			1 st migration	2 nd migration	3 rd migration	3 rd < 2 nd < 1 st & each migration limit
14	6-methoxy-m-toluidine p-cresidine	120-71-8	<0.002	<0.002	<0.002	< 0.002
15	4,4'-methylene-bis-(2-chloro-aniline) 2,2'-dichloro-4,4'-methylene-dianiline	101-14-4	<0.002	<0.002	<0.002	< 0.002
16	4,4'-oxydianiline	101-80-4	<0.002	<0.002	<0.002	< 0.002
17	4,4'-thiodianiline	139-65-1	<0.002	<0.002	<0.002	< 0.002
18	o-toluidine 2-aminotoluene	95-53-4	<0.002	<0.002	<0.002	< 0.002
19	4-methyl-m-phenylenediamine	95-80-7	<0.002	<0.002	<0.002	< 0.002
20	2,4,5-trimethylaniline	137-17-7	<0.002	<0.002	<0.002	< 0.002
21	o-anisidine 2-methoxyaniline	90-04-0	<0.002	<0.002	<0.002	< 0.002
22	4-amino azobenzene	60-09-3	<0.002	<0.002	<0.002	< 0.002
23	1,5- Diaminenaphthalene	2243-62-1	<0.002	<0.002	<0.002	< 0.002
24	Aniline (ANL)	62-53-3	<0.002	<0.002	<0.002	< 0.002
25	2,4-Dimethylaniline (2,4-DMA)	95-68-1	<0.002	<0.002	<0.002	< 0.002
26	2,6-Dimethylaniline (2,6-DMA)	87-62-7	<0.002	<0.002	<0.002	< 0.002
27	m-Phenylenediamine (m-PDA)	108-45-2	<0.002	<0.002	<0.002	< 0.002
28	p-Phenylenediamine (p-PDA)	106-50-3	<0.002	<0.002	<0.002	< 0.002
29	2,6-Toluenediamine (2,6-TDA)	823-40-5	<0.002	<0.002	<0.002	< 0.002

Note:

- “mg/kg” denotes milligram per kilogram foodstuff.
- The specification was quoted from regulation (EU) No. 10/2011 and its amendment (EU) No. 2020/1245.

2.8. SPECIFIC MIGRATION OF N-NITROSAMINES AND N-NITROSATABLE SUBSTANCES FOR RUBBER

Test method: As specified in Resolution AP (2004)4; With reference to to EN 13130-1:2004, followed by Liquid Chromatography with Tandem Mass Spectrometry Detection (LC-MS/MS) analysis.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.

Surface area to Volume ratio: 0.67dm² : 100ml

Test Item	Result [mg/kg]	
	Sample 002	
	Migration N-nitrosamines	Migration N-nitrosatable substances
N-nitrosodimethylamine (NDMA)	< 0.01	< 0.1
N-nitrosodiethylamine (NDEA)	< 0.01	< 0.1
N-nitrosodipropylamine (NDPA)	< 0.01	< 0.1
N-nitrosodiisobutylamine (NDiBA)	< 0.01	< 0.1
N-nitrosodibutylamine (NDBA)	< 0.01	< 0.1
N-nitrosopiperidine (NPIP)	< 0.01	< 0.1
N-nitrosopyrrolidine (NPYR)	< 0.01	< 0.1
N-nitrosomorpholine (NMOR)	< 0.01	< 0.1
N-nitroso N-methyl N-phenylamine (NMPHA)	< 0.01	< 0.1
N-nitroso N-ethyl N-phenylamine (NEPHA)	< 0.01	< 0.1
N-nitroso-N,N-di(3,5,5-trimethylhexyl)amine also known as N-nitrosodiisononylamine (NDiNA)	< 0.01	< 0.1
N-nitrosodibenzylamine (NDBzA)	< 0.01	< 0.1
Sum of above N-nitrosamines and N-nitrosatable substances	< 0.01	< 0.1
Requirement [mg/kg]	Not Detected (< 0.01)	Not Detected (< 0.1)

Note :

- “mg/kg” denotes milligram per kilogram.
- The specification was quoted from Resolution AP (2004)4.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.

Surface area to Volume ratio: 0.66dm² : 100ml

Test Item	Result [mg/kg]	
	Sample 004	
	Migration N-nitrosamines	Migration N-nitrosatable substances
N-nitrosodimethylamine (NDMA)	< 0.01	< 0.1
N-nitrosodiethylamine (NDEA)	< 0.01	< 0.1
N-nitrosodipropylamine (NDPA)	< 0.01	< 0.1
N-nitrosodiisobutylamine (NDiBA)	< 0.01	< 0.1
N-nitrosodibutylamine (NDBA)	< 0.01	< 0.1
N-nitrosopiperidine (NPIP)	< 0.01	< 0.1
N-nitrosopyrrolidine (NPYR)	< 0.01	< 0.1
N-nitrosomorpholine (NMOR)	< 0.01	< 0.1
N-nitroso N-methyl N-phenylamine (NMPPhA)	< 0.01	< 0.1
N-nitroso N-ethyl N-phenylamine (NEPhA)	< 0.01	< 0.1
N-nitroso-N,N-di(3,5,5-trimethylhexyl)amine also known as N-nitrosodiisononylamine (NDiNA)	< 0.01	< 0.1
N-nitrosodibenzylamine (NDBzA)	< 0.01	< 0.1
Sum of above N-nitrosamines and N-nitrosatable substances	< 0.01	< 0.1
Requirement [mg/kg]	Not Detected (< 0.01)	Not Detected (< 0.1)

Note :

- “mg/kg” denotes milligram per kilogram.
- The specification was quoted from Resolution AP (2004)4.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.
 Surface area to Volume ratio: 0.67dm² : 100ml

Test Item	Result [mg/kg]	
	Sample 005	
	Migration N-nitrosamines	Migration N-nitrosatable substances
N-nitrosodimethylamine (NDMA)	< 0.01	< 0.1
N-nitrosodiethylamine (NDEA)	< 0.01	< 0.1
N-nitrosodipropylamine (NDPA)	< 0.01	< 0.1
N-nitrosodiisobutylamine (NDiBA)	< 0.01	< 0.1
N-nitrosodibutylamine (NDBA)	< 0.01	< 0.1
N-nitrosopiperidine (NPIP)	< 0.01	< 0.1
N-nitrosopyrrolidine (NPYR)	< 0.01	< 0.1
N-nitrosomorpholine (NMOR)	< 0.01	< 0.1
N-nitroso N-methyl N-phenylamine (NMPPhA)	< 0.01	< 0.1
N-nitroso N-ethyl N-phenylamine (NEPhA)	< 0.01	< 0.1
N-nitroso-N,N-di(3,5,5-trimethylhexyl)amine also known as N-nitrosodiisononylamine (NDiNA)	< 0.01	< 0.1
N-nitrosodibenzylamine (NDBzA)	< 0.01	< 0.1
Sum of above N-nitrosamines and N-nitrosatable substances	< 0.01	< 0.1
Requirement [mg/kg]	Not Detected (< 0.01)	Not Detected (< 0.1)

Note :

- “mg/kg” denotes milligram per kilogram.
- The specification was quoted from Resolution AP (2004)4.

2.9. TOTAL 1,3-BUTADIENE CONTENT TEST FOR NBR

Test method: As specified in Resolution AP (2004)4; organic solvent extraction, followed by Gas Chromatography/Mass Spectrometry (GC-MS) analysis.

Test Item	CAS No.	Result [mg/kg]	Requirement [mg/kg]
		Sample 004	
Total 1,3-butadiene content	106-99-0	< 0.2	≤ 1

Note:

- “mg/kg” denotes milligram per kilogram foodstuff.
- The specification was quoted from Resolution AP (2004)4.

2.10. SPECIFIC MIGRATION OF 1,3-BUTADIENE TEST FOR NBR

Test method: As specified in Resolution AP (2004)4; the sample(s) were migrated with food simulant, followed by Gas Chromatography/Mass Spectrometry (GC-MS) analysis.

Testing condition and simulant: 20% Ethanol at 40 °C for 10 days.

Surface area to Volume ratio: 0.631dm² : 105ml

Test Item	CAS No.	Result [mg/kg]	Requirement [mg/kg]
		Sample 004	
Migration of 1,3-butadiene	106-99-0	< 0.01	Not Detected (< 0.01)

Note:

- “mg/kg” denotes milligram per kilogram foodstuff.
- The specification was quoted from Resolution AP (2004)4.

2.11. SPECIFIC MIGRATION OF 22 HEAVY METALS TEST FOR METAL AND METAL ALLOY

Test method: The sample(s) were extracted with food simulant, followed by Inductively Coupled Plasma Mass Spectrometry(ICP-MS) analysis.

Testing condition and simulant: artificial tap water at 40 °C for 10 days.

Surface area to Volume ratio: 0.028 dm² : 125 ml

No.	Test Item		Result [mg/kg]		Requirement [mg/kg]	
			Sample 006		1 st +2 nd migration	3 rd migration
			1 st +2 nd migration	3 rd migration		
1.	Barium	(Ba)	<0.2	<0.1	≤ 8.4	≤ 1.2
2.	Copper	(Cu)	<0.2	<0.1	≤ 28	≤ 4
3.	Iron	(Fe)	<0.2	<0.1	≤ 280	≤ 40
4.	Tin	(Sn)	<1.0	<0.5	≤ 700	≤ 100
5.	Chromium	(Cr)	<0.1	<0.05	≤ 7	≤ 1
6.	Manganese	(Mn)	<0.2	<0.1	≤ 3.85	≤ 0.55
7.	Zinc	(Zn)	<0.2	<0.1	≤ 35	≤ 5
8.	Aluminum	(Al)	<0.2	<0.1	≤ 35	≤ 5
9.	Lithium	(Li)	<0.01	<0.005	≤ 0.336	≤ 0.048
10.	Beryllium	(Be)	<0.004	<0.002	≤ 0.07	≤ 0.01
11.	Vanadium	(V)	<0.004	<0.002	≤ 0.07	≤ 0.01
12.	Nickel	(Ni)	<0.1	<0.05	≤ 0.98	≤ 0.14
13.	Cobalt	(Co)	<0.004	<0.002	≤ 0.14	≤ 0.02
14.	Arsenic	(As)	<0.0008	<0.0004	≤ 0.014	≤ 0.002
15.	Molybdenum	(Mo)	<0.004	<0.002	≤ 0.84	≤ 0.12
16.	Silver	(Ag)	<0.004	<0.002	≤ 0.56	≤ 0.08
17.	Cadmium	(Cd)	<0.0008	<0.0004	≤ 0.035	≤ 0.005
18.	Antimony	(Sb)	<0.01	<0.005	≤ 0.28	≤ 0.04
19.	Mercury	(Hg)	<0.001	<0.0005	≤ 0.021	≤ 0.003
20.	Thallium	(Tl)	<0.0002	<0.0001	≤ 0.007	≤ 0.001
21.	Lead	(Pb)	<0.02	<0.01	≤ 0.07	≤ 0.010
22.	Zirconium	(Zr)	<0.02	<0.01	≤ 14	≤ 2

Note:

- “mg/kg” denotes milligram per kilogram foodstuff.
- The specification was quoted from European Directorate for the Quality of Medicines & Healthcare Technical guide Resolution CM/Res(2020)9.



2.12. SENSORY TEST

Test method: With reference to DIN 10955: 2024. The submitted sample was treated with food stimulant. After this treatment, examined by panels with regard to any divergence in smell and taste.

Testing condition and simulant: Distilled water at 40 °C for 10 days.

No. of Judges: 6 panel

Test Item	Grading Result		Recommended Level
	Sample 001	Sample 002	
Transfer of Smell	0	0	< 3
Transfer of Taste	0	0	< 3

Test Item	Grading Result		Recommended Level
	Sample 003	Sample 004	
Transfer of Smell	0	0	< 3
Transfer of Taste	0	0	< 3

Test Item	Grading Result		Recommended Level
	Sample 005	Sample 006	
Transfer of Smell	0	0	< 3
Transfer of Taste	0	0	< 3

Note:

- Explanation for grading are listed as below:
 Grading 0: No perceptible taste/smell deviation
 Grading 1: Just perceptible taste/smell deviation
 Grading 2: Weak taste/smell deviation
 Grading 3: Clear taste/smell deviation
 Grading 4: Strong taste/smell deviation

-----End of Report-----