

Test Report

No.: NGBHL24004760301

Date: Aug 29, 2024

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Client Name:

Client Address:

Sample Description: STAINLESS STEEL WATER BOTTLE AND WATER BOTTLE LID

Style No.: NOT PROVIDED

Item No.: NOT PROVIDED

The above sample(s) and information were provided by the client.

SGS No.: NBHL2408017444CW

Sample Receiving Date: Aug 20, 2024

Testing Period: Aug 20, 2024 ~ Aug 29, 2024

Test Requested: Select test(s) as requested by the client.

Testing Performed: Follow selected test(s) as requested by client.

	Test Requirement	Comment
1	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Sensorial examination odour and taste test	Pass
2	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Colour release	Pass
3	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Polynuclear aromatic hydrocarbons (PAHs)	Pass
4	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation and BfR recommendation - Overall migration	Pass

Signed for and on behalf of

SGS-CSTC Standards Technical Services Co., Ltd. Ningbo Branch

Hedy Hu

Hedy Hu

Approved Signatory

SGS-CSTC Standards Technical Services Co., Ltd.
Ningbo Branch Chemical Laboratory

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	Test Requirement	Comment
5	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation and BfR recommendation - Specific migration of heavy metals	Pass
6	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation and BfR recommendation - Specific migration of primary aromatic amine (individual)	Pass
7	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Extractable Components	Pass
8	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Volatile Organic Matter(VOM)	Pass
9	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Total Platinum(Pt)	Pass
10	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Total Lead and Cadmium	Pass
11	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments, European Directorate for the Quality of Medicines & Healthcare (EDQM) - Technical Guide on Metals and alloys used in food contact materials and articles (2nd edition, 2024) - Extractable Heavy Metals	Pass

Test Result(s):

Test Part Description:

SN ID	Sample No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	A1	NGB24-0047603-0001.C001	Black plastic lid	PP COPOLYMER
SN2	A2	NGB24-0047603-0001.C002	Silvery metal bottle inner	STAINLESS STEEL
SN3	A3	NGB24-0047603-0001.C003	Milky silicone rubber ring	SILICONE RUBBER

Remarks:

- (1) mg/dm² = milligram per square decimeter
mg/inch² = milligram per square inches
μg/cm² = microgram per square centimeter



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mg/L = milligram per litre
mg/kg = milligram per kilogram

- (2) °C = degree Celsius
°F = degree Fahrenheit
(3) <= less than
(4) RL = Reporting Limit
(5) ND = Not Detected (< RL).

The ratio of surface area to volume

Sample No	Overall Migration	Specific Migration
A1	8.2 dm ² /kg	6.0 dm ² /kg

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Sensorial examination odour and taste test

Test Method: With reference to DIN 10955: 2024.
No. of panelist: 6

Test Media	Test Condition
	A1
Distilled water	100°C, 2 hrs

Test Item(s)	Limit	Unit(s)	A1
Area/Volume	-	dm ² /kg	8.2
Sensorial examination odour	2.5	-	0.0
Sensorial examination taste	2.5	-	0.0
Comment			Pass

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, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Colour release

Test Method: With reference to Kunststoffe im Lebensmittelverkehr, Part B II IX.



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Simulant used	Limit	A1	Comment
2% acetic acid (W/W)	No colour release	Negative	Pass
Coconut Oil	No colour release	Negative	Pass

Notes:

(1) Negative = No color release observed, Positive = Color release observed.

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Polynuclear aromatic hydrocarbons (PAHs)

Test Method: With reference to AfPS GS 2019:01 PAK, analysis was performed by GC-MS.

Test Item(s)	CAS No.	Limit	Unit(s)	RL	A1	A3
Benzo(a)pyrene(BaP)	50-32-8	0.2	mg/kg	0.2	ND	ND
Benzo(e)pyrene(BeP)	192-97-2	0.2	mg/kg	0.2	ND	ND
Benzo(a)anthracene(BaA)	56-55-3	0.2	mg/kg	0.2	ND	ND
Benzo(b)fluoranthene(BbF)	205-99-2	0.2	mg/kg	0.2	ND	ND
Benzo(j)fluoranthene(BjF)	205-82-3	0.2	mg/kg	0.2	ND	ND
Benzo(k)fluoranthene(BkF)	207-08-9	0.2	mg/kg	0.2	ND	ND
Chrysene(CHR)	218-01-9	0.2	mg/kg	0.2	ND	ND
Dibenzo(a,h)anthracene(DBA)	53-70-3	0.2	mg/kg	0.2	ND	ND
Benzo(g,h,i)perylene(BPE)	191-24-2	0.2	mg/kg	0.2	ND	ND
Indeno(1,2,3-c,d)pyrene(IPY)	193-39-5	0.2	mg/kg	0.2	ND	ND
Phenanthrene(PHE)	85-01-8	0.2	mg/kg	0.2	ND	ND
Pyrene(PYR)	129-00-0	0.2	mg/kg	0.2	ND	ND
Anthracene(ANT)	120-12-7	0.2	mg/kg	0.2	ND	ND
Fluoranthene(FLT)	206-44-0	0.2	mg/kg	0.2	ND	ND
Naphthalene(NAP)	91-20-3	0.2	mg/kg	0.2	ND	ND
Acenaphthylene(ANY)	208-96-8	0.2	mg/kg	0.2	ND	ND
Acenaphthene(ANA)	83-32-9	0.2	mg/kg	0.2	ND	ND
Fluorene(FLU)	86-73-7	0.2	mg/kg	0.2	ND	ND
Comment					Pass	Pass

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation and BfR recommendation - Overall migration



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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; EN 1186-3:2022 Test methods for overall migration in evaporable simulants

Test Condition		
	20% Ethanol(V/V)	3% Acetic acid (W/V)
A1	100°C, 1 hr	100°C, 1 hr

Simulant used	Limit	Unit(s)	RL	A1 (1 st Migration)	A1 (2 nd Migration)	A1 (3 rd Migration)	Stability	Comment
20% Ethanol(V/V)	10	mg/dm ²	3.0	ND	ND	ND	Compliant	Pass
3% Acetic acid (W/V)	10	mg/dm ²	3.0	ND	ND	ND	Compliant	Pass

Notes:

- (1) Analytical tolerance of evaporable simulants is 2 mg/dm² or 12 mg/kg, analytical tolerance of olive oil simulant is 3 mg/dm² or 20 mg/kg.
- (2) Test condition & simulant were specified by client.
- (3) For repeated use, compliance of the material or article is verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test.
- (4) Total food contact surface area of whole article (i.e. sealed container with cap, gaskets, stopper or similar sealing article) is applied in the calculation of the result according to Commission Regulation (EU) No 10/2011 of 14 January 2011 Article 17.

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Test Method: With reference to EN 13130-1:2004, analysis was performed by ICP-MS.

Simulant	Test Condition
	A1
3% Acetic acid (W/V)	100°C, 2 hrs

Test Item(s)	Limit	Unit(s)	RL	A1		
3% Acetic acid (W/V)						
Migration times				First	Second	Third
Arsenic(As)	ND	mg/kg	0.01	ND	ND	ND
Cadmium(Cd)	ND	mg/kg	0.002	ND	ND	ND
Chromium(Cr)	ND	mg/kg	0.01	ND	ND	ND
Mercury(Hg)	ND	mg/kg	0.01	ND	ND	ND



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Test Item(s)	Limit	Unit(s)	RL	A1		
Lead(Pb)	ND	mg/kg	0.01	ND	ND	ND
Aluminium(Al)	1	mg/kg	0.1	ND	ND	ND
Barium(Ba)	1	mg/kg	0.25	ND	ND	ND
Cobalt(Co)	0.05	mg/kg	0.01	ND	ND	ND
Copper(Cu)	5	mg/kg	0.25	ND	ND	ND
Iron(Fe)	48	mg/kg	5	ND	ND	ND
Lithium(Li)	0.6	mg/kg	0.1	ND	ND	ND
Manganese(Mn)	0.6	mg/kg	0.1	ND	ND	ND
Zinc(Zn)	5	mg/kg	0.5	ND	ND	ND
Nickel(Ni)	0.02	mg/kg	0.01	ND	ND	ND
Antimony(Sb)	0.04	mg/kg	0.01	ND	ND	ND
Europium(Eu)	-	mg/kg	0.025	ND	ND	ND
Gadolinium(Gd)	-	mg/kg	0.025	ND	ND	ND
Lanthanum(La)	-	mg/kg	0.025	ND	ND	ND
Terbium(Tb)	-	mg/kg	0.025	ND	ND	ND
Europium(Eu)+ Gadolinium(Gd)+ Lanthanum(La)+ Terbium(Tb)	0.05	mg/kg	-	ND	ND	ND
Stability	-	-	-	Compliant		
Comment				Pass		

Notes:

- (1) Test condition & simulant were specified by client.
- (2) For repeated use, compliance of the material or article is verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test. For substances which limit is "Not Detected", the compliance is based on the first migration test result if it is detected.

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Test Method: With reference to EN 13130-1:2004, analysis was performed by LC-MS-MS.

Simulant	Test Condition
	A1
3% Acetic acid (W/V)	100°C, 2 hrs

Test Item(s)	CAS No.	Limit	Unit(s)	RL	A1		
3% Acetic acid (W/V)							
Migration times					First	Second	Third
2,4,5-Trimethylaniline	137-17-7	ND	mg/kg	0.002	ND	ND	ND
2,4-Toluenediamine(2,4-TDA)	95-80-7	ND	mg/kg	0.002	ND	ND	ND
2-Methoxy-5-methylaniline	120-71-8	ND	mg/kg	0.002	ND	ND	ND



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3,3'-Dimethylbenzidine	119-93-7	ND	mg/kg	0.002	ND	ND	ND
4,4'-Diaminodiphenyl ether	101-80-4	ND	mg/kg	0.002	ND	ND	ND
4,4'-Methylenedianiline	101-77-9	ND	mg/kg	0.002	ND	ND	ND
4,4'-Methylenedio-toluidine	838-88-0	ND	mg/kg	0.002	ND	ND	ND
4-Aminobiphenyl	92-67-1	ND	mg/kg	0.002	ND	ND	ND
4-Chloroaniline	106-47-8	ND	mg/kg	0.002	ND	ND	ND
4-Chloro-o-toluidine	95-69-2	ND	mg/kg	0.002	ND	ND	ND
4-Methoxy-m-phenylenediamine	615-05-4	ND	mg/kg	0.002	ND	ND	ND
Benzidine	92-87-5	ND	mg/kg	0.002	ND	ND	ND
o-Anisidine	90-04-0	ND	mg/kg	0.002	ND	ND	ND
o-Toluidine	95-53-4	ND	mg/kg	0.002	ND	ND	ND
2-Naphthylamine	91-59-8	ND	mg/kg	0.002	ND	ND	ND
o-Aminoazotoluene	97-56-3	ND	mg/kg	0.002	ND	ND	ND
3,3'-Dichlorobenzidine	91-94-1	ND	mg/kg	0.002	ND	ND	ND
3,3'-Dimethoxybenzidine	119-90-4	ND	mg/kg	0.002	ND	ND	ND
4,4'-Methylenebis-(2-chloroaniline)	101-14-4	ND	mg/kg	0.002	ND	ND	ND
4,4'-Thiodianiline	139-65-1	ND	mg/kg	0.002	ND	ND	ND
4-Aminoazobenzene	60-09-3	ND	mg/kg	0.002	ND	ND	ND
1,3-Phenylenediamine	108-45-2	ND	mg/kg	0.002	ND	ND	ND
2-Amino-4-nitrotoluene	99-55-8	ND	mg/kg	0.002	ND	ND	ND
Primary aromatic amine(other)	-	0.01	mg/kg	-	ND	ND	ND
1,3-Diiminoisoindoline	3468-11-9	-	mg/kg	0.010	ND	ND	ND
3-Anisidine	536-90-3	-	mg/kg	0.002	ND	ND	ND
2-Amino-1-naphthalenesulfonic acid	81-16-3	-	mg/kg	0.005	ND	ND	ND
2-Ethoxyaniline	94-70-2	-	mg/kg	0.005	ND	ND	ND



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Test Item(s)	CAS No.	Limit	Unit(s)	RL	A1		
5-Chloro-2-methoxyaniline	95-03-4	-	mg/kg	0.005	ND	ND	ND
2-Chloraniline	95-51-2	-	mg/kg	0.010	ND	ND	ND
4-Toluidine	106-49-0	-	mg/kg	0.002	ND	ND	ND
1,4-Phenylenediamine	106-50-3	-	mg/kg	0.002	ND	ND	ND
3-Chloroaniline	108-42-9	-	mg/kg	0.010	ND	ND	ND
3-Toluidine	108-44-1	-	mg/kg	0.002	ND	ND	ND
3-Amino-4-methoxybenzanilide	120-35-4	-	mg/kg	0.002	ND	ND	ND
2-Chloro-4-nitroaniline	121-87-9	-	mg/kg	0.005	ND	ND	ND
4-Chlor-3-methoxyaniline	13726-14-2	-	mg/kg	0.005	ND	ND	ND
4-Ethoxyaniline	156-43-4	-	mg/kg	0.002	ND	ND	ND
3-Amino-4-methylbenzamide	19406-86-1	-	mg/kg	0.002	ND	ND	ND
1,5-Diaminonaphthalene	2243-62-1	-	mg/kg	0.002	ND	ND	ND
4-Aminobenzamide	2835-68-9	-	mg/kg	0.005	ND	ND	ND
Aniline	62-53-3	-	mg/kg	0.002	ND	ND	ND
4-Chlor-2,5-dimethoxyaniline	6358-64-1	-	mg/kg	0.005	ND	ND	ND
2,4,5-Trichloroaniline	636-30-6	-	mg/kg	0.010	ND	ND	ND
5-Amino-6-methylbenzimidazole	67014-36-2	-	mg/kg	0.005	ND	ND	ND
2,6-Diaminotoluene	823-40-5	-	mg/kg	0.002	ND	ND	ND
2,6-Dimethylaniline(2,6-DMA)	87-62-7	-	mg/kg	0.002	ND	ND	ND
4-Aminotoluene-3-sulfonic acid	88-44-8	-	mg/kg	0.005	ND	ND	ND
1,2-Phenylenediamine	95-54-5	-	mg/kg	0.002	ND	ND	ND
2,4-Dimethylaniline(2,4-DMA)	95-68-1	-	mg/kg	0.002	ND	ND	ND
5-Chloro-2-methylaniline	95-79-4	-	mg/kg	0.005	ND	ND	ND
2,5-Dichloroaniline	95-82-9	-	mg/kg	0.010	ND	ND	ND
2,4-Dinitroaniline	97-02-9	-	mg/kg	0.005	ND	ND	ND



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Test Item(s)	CAS No.	Limit	Unit(s)	RL	A1		
2-Methoxy-4-nitroaniline	97-52-9	-	mg/kg	0.005	ND	ND	ND
p-Anisidine	104-94-9	-	mg/kg	0.002	ND	ND	ND
Dimethyl aminoterephthalate	5372-81-6	-	mg/kg	0.002	ND	ND	ND
3,4-Dichloroaniline	95-76-1	-	mg/kg	0.002	ND	ND	ND
1-Naphthylamine	134-32-7	-	mg/kg	0.002	ND	ND	ND
2-Aminobiphenyl	90-41-5	-	mg/kg	0.002	ND	ND	ND
Butyl anthranilate	7756-96-9	-	mg/kg	0.002	ND	ND	ND
2,4'-Diaminodiphenyl methane	1208-52-2	-	mg/kg	0.002	ND	ND	ND
2-Amino-5-methylbenzoic acid	2941-78-8	-	mg/kg	0.002	ND	ND	ND
Stability	-	-	-	-	Compliant		
Comment					Pass		

Notes:

- (1) Test condition & simulant were specified by client.
- (2) For repeated use, compliance of the material or article is verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test. For substances which limit is "Not Detected", the compliance is based on the first migration test result if it is detected.

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Extractable Components

Test Method: With reference to 61st Mitteilung über die Untersuchung von Kunststoffen, Bundesgesundheitsbl 46 (2003) 362.

Simulant used	Test Condition	Limit	Unit(s)	RL	A3	Comment
10% Ethanol(V/V)	100°C, 1 hr	0.5	%(w/w)	0.1	ND	Pass
3% Acetic acid	100°C, 1 hr	0.5	%(w/w)	0.1	ND	Pass
DI water	100°C, 1 hr	0.5	%(w/w)	0.1	ND	Pass

Notes:

- (1) Test condition & simulant were specified by client.
- (2) %(w/w) = percentage of weight by weight

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Volatile Organic Matter(VOM)



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Test Method: With reference to BfR test method-Determination of volatile compounds in silicone consumer products (09/2023).
Test condition: 200°C, 4 hrs

Test Item(s)	Limit	Unit(s)	RL	A3
Volatile organic matter (VOM)	0.5	%(w/w)	0.10	0.38
Comment				Pass

Notes:

(1) %(w/w) = percentage of weight by weight

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Total Platinum(Pt)

Test Method: Acid digestion, analysis was performed by ICP-OES.

Test Item(s)	Limit	Unit(s)	RL	A3
Platinum(Pt)	50	mg/kg	20	ND
Comment				Pass

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments and BfR recommendation - Total Lead and Cadmium

Test Method: Acidic digestion, analysis was performed by ICP-OES.

Test Item(s)	Limit	Unit(s)	RL	A3
Cadmium(Cd)	Absent	mg/kg	2	ND
Lead(Pb)	Absent	mg/kg	2	ND
Comment				Pass

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments, European Directorate for the Quality of Medicines & Healthcare (EDQM) - Technical Guide on Metals and alloys used in food contact materials and articles (2nd edition, 2024) - Extractable Heavy Metals

Test Method: With reference to EN 13130-1:2004, analysis was performed by ICP-MS.

Simulant used:	0.5% Citric acid
Test condition:	100°C, 2 hrs
Area/Volume	6.7dm ² /kg

Test Item(s)	Unit(s)	RL	(1 st +2 nd) Migration		3 rd Migration	
			Limit	A2	Limit	A2
Aluminium (Al)	mg/kg	0.2	35	ND	5	ND
Antimony (Sb)	mg/kg	0.02	0.28	ND	0.04	ND
Chromium(Cr)	mg/kg	0.1	7	ND	1	ND



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Test Item(s)	Unit(s)	RL	(1 st +2 nd) Migration		3 rd Migration	
			Limit	A2	Limit	A2
Cobalt(Co)	mg/kg	0.01	0.14	ND	0.02	ND
Copper(Cu)	mg/kg	0.1	28	ND	4	ND
Iron(Fe)	mg/kg	0.25	280	ND	40	ND
Manganese(Mn)	mg/kg	0.25	3.85	ND	0.55	ND
Molybdenum(Mo)	mg/kg	0.02	0.84	ND	0.12	ND
Nickel(Ni)	mg/kg	0.05	0.98	ND	0.14	ND
Silver(Ag)	mg/kg	0.03	0.56	ND	0.08	ND
Tin(Sn)	mg/kg	5	700	ND	100	ND
Vanadium(V)	mg/kg	0.005	0.07	ND	0.01	ND
Zinc(Zn)	mg/kg	1	35	ND	5	ND
Arsenic(As)	mg/kg	0.001	0.014	ND	0.002	ND
Barium(Ba)	mg/kg	0.25	8.4	ND	1.2	ND
Beryllium(Be)	mg/kg	0.005	0.07	ND	0.01	ND
Cadmium(Cd)	mg/kg	0.002	0.035	ND	0.005	ND
Lead(Pb)	mg/kg	0.005	0.07	ND	0.01	ND
Lithium(Li)	mg/kg	0.02	0.336	ND	0.048	ND
Mercury(Hg)	mg/kg	0.002	0.021	ND	0.003	ND
Thallium(Tl)	mg/kg	0.0001	0.007	ND	0.001	ND
Zirconium(Zr)	mg/kg	0.2	14	ND	2	ND
Comment			Pass			

Notes:

- (1) Test condition & simulant were specified by client.
- (2) Requirement for repeat use article: According to European Directorate for the Quality of Medicines & Healthcare (EDQM), the result from 3rd migration shall comply with the Specific Release Limit (SRL) and the sum of 1st and 2nd migration shall not exceed seven times of SRL for repeated use articles.

Unless otherwise stated, the decision rule for conformity reporting is based on Binary Statement for Simple Acceptance Rule ($w=0$) stated in ILAC-G8:09/2019.



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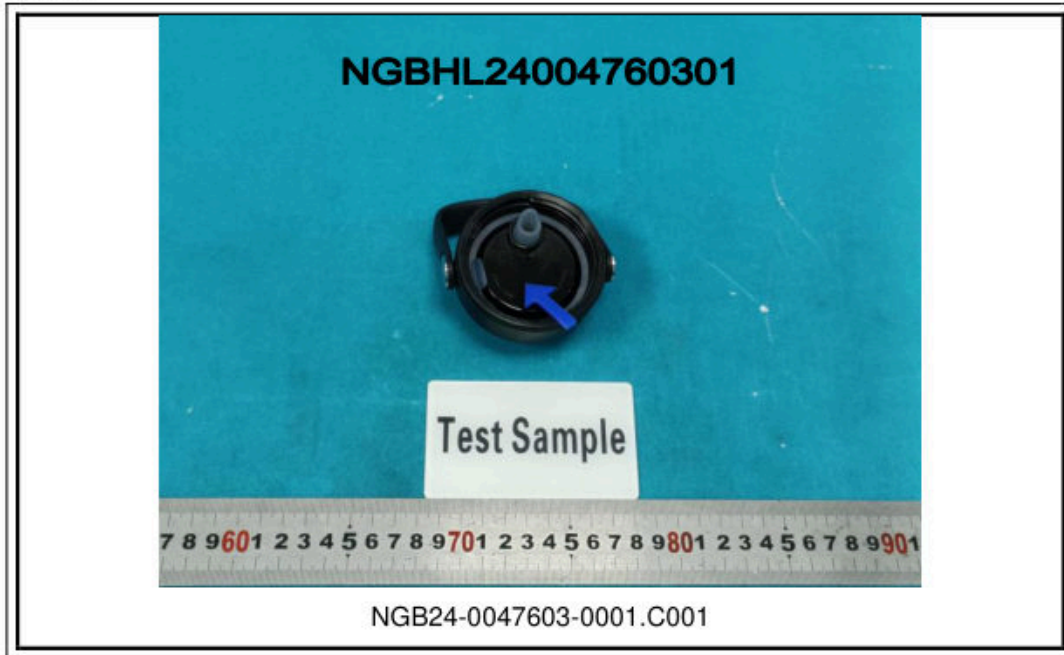
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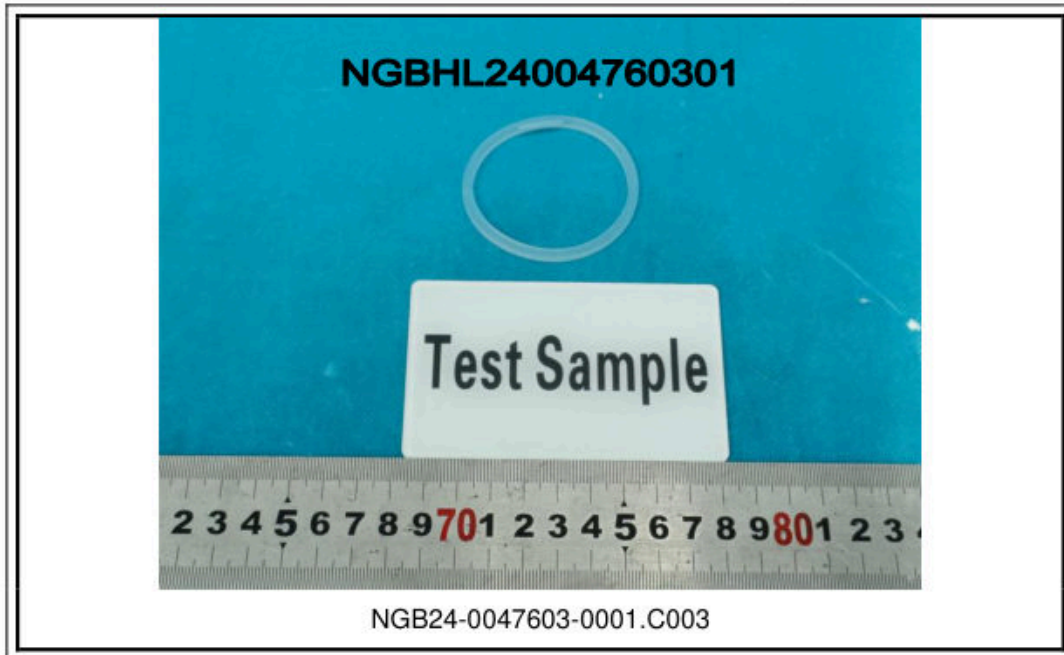
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