

Test Report

No.: SHAAF24002941232

Date: Mar 29, 2024

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Client Name: Membrane Solutions New Material Technology (NanTong)Co.ltd
 Client Address: No.159.Mudaniiang Road.Rudong County EconomicDevelopment Zone Nantong CityJianasu Province PR.China

Sample Name: NY Cartridge Filter

Production Date: 2024-2-1

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

SGS Job No.: O-SHAFL202400317226 ASH24-0008999

Sample Receiving Date: Feb 21, 2024

Testing Period: Feb 21, 2024 ~ Feb 28, 2024

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

Test Method(s): Please refer to next page(s).

Test Result(s): Please refer to next page(s).

	Test Requirement	Comment
1	US FDA 21 CFR 177.1520 - Density at 23°C	Pass
2	US FDA 21 CFR 177.1520 - Extractable fraction	Pass
3	US FDA 21 CFR 177.1520 - Soluble fraction in Xylene	Pass
4	US FDA 21 CFR 177.1520 - Melting Point	Pass
5	US FDA 21 CFR 177.1500 - Specific Gravity at 23°C	Pass
6	US FDA 21 CFR 177.1500 - Solubility in Boiling 4.2N HCl	Pass
7	US FDA 21 CFR 177.1500 - Maximum Extractable Fraction	Pass
8	US FDA 21 CFR 177.1210 - Chloroform-Soluble Extractives	Pass

Signed for and on behalf of
 SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Annie Liu

Annie Liu
 Approved Signatory

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Test Result(s):

Test Part Description:

SN ID	Sample No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	A2	SHA24-0029412-0001.C002	Semi transparent plastic solid	PP
SN2	A3	SHA24-0029412-0001.C003	White film	PA6
SN3	A8	SHA24-0029412-0001.C008	White film	PP
SN4	A9	SHA24-0029412-0001.C009	Red sealing ring	Silicone Rubber

Remarks:

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

US FDA 21 CFR 177.1520 - Density at 23°C

Test Method: With reference to US FDA 21 CFR 177.1520d(1).

Test Item(s)	Limit	Unit(s)	A2
Density at 23°C	0.85-1.00	g/cm ³	0.897
Comment			Pass

Test Item(s)	Limit	Unit(s)	A8
Density at 23°C	0.880-0.913	g/cm ³	0.897
Comment			Pass

US FDA 21 CFR 177.1520 - Extractable fraction

Test Method: With reference to US FDA 21 CFR 177.1520(d)(3)(ii).

Simulant used	Test Condition	Limit	Unit(s)	RL	A2	Comment
n-Hexane	50°C, 2 hrs	5.5	%(w/w)	0.1	ND	Pass

Test Method: With reference to US FDA 21 CFR 177.1520(d) 3 (i).



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Simulant used	Test Condition	Limit	Unit(s)	RL	A8	Comment
n-Hexane	Reflux Temperature, 2 hrs	6.4	%(w/w)	0.5	ND	Pass

US FDA 21 CFR 177.1520 - Soluble fraction in Xylene

Test Method: With reference to US FDA 21 CFR 177.1520(d)(4)(ii).

Test Item(s)	Limit	Unit(s)	RL	A2
Soluble Fraction in Xylene	30	%(w/w)	0.5	10.8
Comment				Pass

Test Method: With reference to US FDA 21 CFR 177.1520 (d) 4 (i).

Test Item(s)	Limit	Unit(s)	RL	A8
Soluble Fraction in Xylene	9.8	%(w/w)	0.5	7.5
Comment				Pass

US FDA 21 CFR 177.1520 - Melting Point

Test Method: With reference to US FDA 21 CFR 177.1520 (d) (2).

Test Item(s)	Limit	Unit(s)	A8
Melting Point	160-180	°C	166.2
Comment			Pass

Notes:

These tests were subcontracted to SGS Ningbo Chemical Lab.

US FDA 21 CFR 177.1500 - Specific Gravity at 23°C

Test Method: With reference to US FDA 21 CFR 177.1500.

Test Item(s)	Limit	Unit(s)	A3
Specific Gravity at 23°C	1.135-1.165	g/cm ³	1.143
Comment			Pass

US FDA 21 CFR 177.1500 - Solubility in Boiling 4.2N HCl

Test Method: With reference to US FDA 21 CFR 177.1500.

Test Item(s)	Limit	A3
Solubility in Boiling 4.2N HCl	Dissolves in 1 hour	Dissolved
Comment		Pass

US FDA 21 CFR 177.1500 - Maximum Extractable Fraction



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Test Method: With reference to US FDA 21 CFR 177.1500.

Simulant used	Test Condition	Limit	Unit(s)	RL	A3	Comment
95% Ethanol	Reflux Temperature, 8 hrs	2.0	%(w/w)	0.05	0.11	Pass
Benzene	Reflux Temperature, 8 hrs	1.0	%(w/w)	0.05	ND	Pass
Ethyl Acetate	Reflux Temperature, 8 hrs	1.0	%(w/w)	0.05	ND	Pass
Distilled water	Reflux Temperature, 8 hrs	1.0	%(w/w)	0.05	ND	Pass

US FDA 21 CFR 177.1210 - Chloroform-Soluble Extractives

Test Method: With reference to US FDA 21 CFR 177.1210.

Simulant used	Test Condition	Limit	Unit(s)	RL	A9	Comment
n-Heptane	150°F, 2 hrs	50	mg/kg	5	ND	Pass
Distilled water	250°F, 2 hrs	50	mg/kg	5	ND	Pass

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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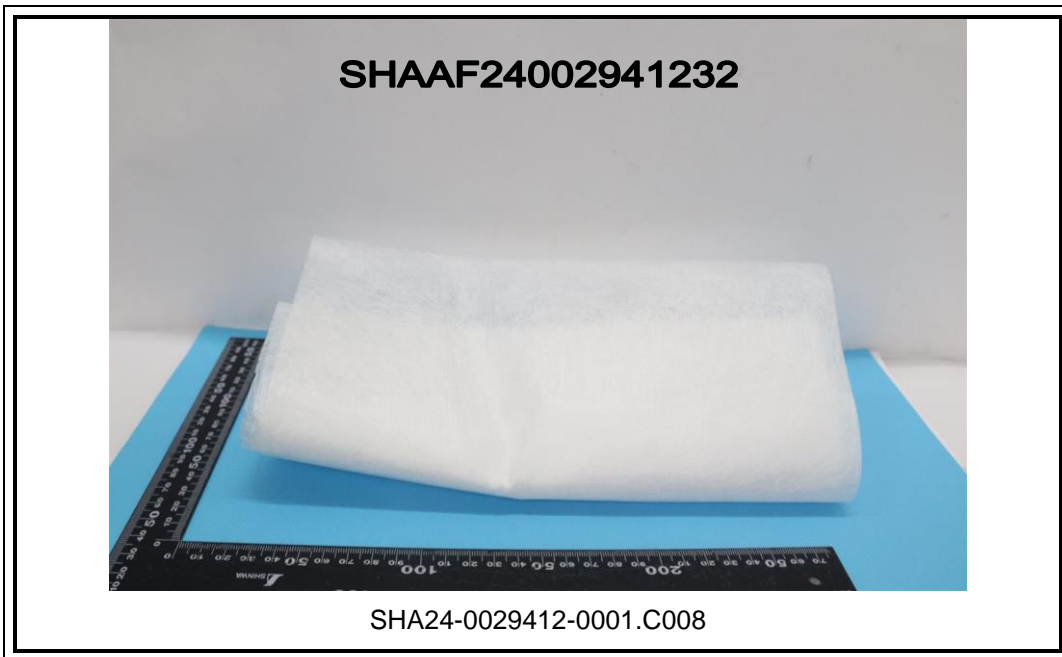
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