

Test Report

No. SHAHG1821595401

Date: 28 Sep 2018

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HANGZHOU DEEFINE FILTRATION TECHNOLOGY CO., LTD

NO.32 XIANXING ROAD, XIANLIN INDYSTRIAL PARK, YUHANG DISTRIC, HANGZHOU

The following sample(s) was/were submitted and identified on behalf of the clients as : POLYPROPYLENE FOLDER FILTER CARTRIDGE

SGS Job No. : SHHL1809052912CW - SH
 Style No. : DEEFINE-PP
 Manufacturer : HANGZHOU DEEFINE FILTRATION TECHNOLOGY CO., LTD
 Country of Origin : CHINA
 Country of Destination : USA
 Date of Sample Received : 21 Sep 2018
 Testing Period : 21 Sep 2018 - 28 Sep 2018
 Test Requested : Selected test(s) as requested by client.
 Test Method : Please refer to next page(s).
 Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
FDA 21 CFR 177.1520- Extractable fraction	PASS
FDA 21 CFR 177.1520- Soluble fraction in Xylene	PASS
FDA 21 CFR 177.1520- Density at 23°C	See Results
FDA 21 CFR 177.1520- Melting point	PASS

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



Jenny Yao
 Approved Signatory



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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	SHA18-215954.001	White pp filter cartridge	PP

Remarks :

- (1) mg/dm² = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C= degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected (< MDL)

FDA 21 CFR 177.1520- Extractable fraction

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

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 001</u>	<u>Conclusion</u>
n-hexane	2hr(s)	Reflux temperature	6.4% (w/w)	1.1% (w/w)	PASS

FDA 21 CFR 177.1520- Soluble fraction in Xylene

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

<u>Test Item(s)</u>	<u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>001</u>	<u>Conclusion</u>
Soluble fraction in Xylene	9.8	% (w/w)	0.5	<0.5	PASS

FDA 21 CFR 177.1520- Density at 23°C

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



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<u>Test Item(s)</u>	<u>Limit</u>	<u>001</u>
Density at 23°C, g/ cm ³	0.880-0.913	0.717#

Notes :

Test result is only for reference

The FDA tests are intended for the raw/virgin polymer material. Since this was not available, the finished article was tested, and this testing included the polymer and all the other substances that were added during the manufacturing process. It is recommended that the physical parameters be tested on the raw/virgin polymer material.

FDA 21 CFR 177.1520- Melting point

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

<u>Test Item(s)</u>	<u>Limit</u>	<u>001</u>
Melting point, °C*	160-180	160.4
Conclusion		PASS

Notes :

(1) *The test was subcontracted to SGS Ningbo chemical lab.

Remark:

#=Exceed the limit.



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