

M SEALS FC050

Food Contact Compliant Virgin PTFE P1000/PTFE 598

MATERIAL DATA SHEET (Version 6.0 – 05.2022)



- Part of Diploma PLC



FDA 177.1550
Compliant



3-A Sanitary
20-27



(EC) 1935/2004 Compliant
(EC) 10/2011 Compliant
GB4806.1, 6 & 7 Compliant
GB9685 Compliant



ADI FREE



USP <88> +121°C
Class VI Compliant



WRAS / BS6920-1 (85°C)
DVGW270
KTW (85°C)
NSF61
ACS DGS/VS4 No 99/217
ACS DGS/VS4 No 2000/232

Description

M Seals material FC050 is a virgin PTFE material compliance tested for food contact, potable water, sanitary and pharmaceutical applications.

The material has been successfully extraction tested in accordance with FDA, EC 10/2011 methods and complies with Chinese regulations for materials in repeated contact with foodstuffs and meets the requirements of 3-A sanitary, USP VI standards and multiple international potable water standards.

These fantastic attributes make FC050 the first choice for PTFE seals and other parts which may require excellent chemical and/or fluid compatibility along with international standards compliance.

Physical Properties

Property	Test method	Unit	Typical Value
Colour			White
Specific Gravity	ASTM D792	g/cm ³	2.13 - 2.19
Hardness	ASTM D2240	Shore D	≥54
Tensile strength	ASTM D4894	MPa	≥20
Elongation	ASTM D4894	%	≥200
Modulus 100%	DIN 53504	Mpa	≥10
Deformation under load (24 Hours @ 23°C / 140 Kg/cm ²)	ASTM D621	%	10 - 13
Permanent deformation (24 Hours relaxation @ 23°C)	ASTM D621	%	6 - 7.5
Minimum service temperature		°C	-200
Maximum service temperature		°C	+250

Main Characteristics

- CFR 177.1550 FDA compliant
- 3-A compliant
- (EC) 1935/2004 & (EC) 10/2011 compliant
- USP VI compliant
- Compliance with Chinese food contact regulations
- International potable water approval (WRAS / DVG W270 / KTW Etc.)
- ADI free

Typical Products

- Clamp seals
- Sanitary seals
- O-Rings
- Back-up Rings
- Spring energised seals
- Soft seat seals
- Bespoke Parts

Please see the following page for FDA & (EC) 10/2011 migration results

3-A Sanitary results are available, please ask for test report 001/2017

USP VI results are available, please ask for test report 16-03697 G1

Tel: 0044 (0) 114 243 2777 . Fax: 0044 (0) 114 242 2300 . Mail: sales.esd@m-seals.co.uk . Web: www.m-seals.com

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Overall migration results of <u>fluorides</u> into food simulant on FC050 material samples (mg/inch ²)				
FDA test method	Reflux test conditions	Result	Limit*	Conclusion
FDA 177.1550	distilled water, 2 hours	<0.003	0.03	PASS
FDA 177.1550	ethanol 50%, 2 hours	<0.007	0.03	PASS
FDA 177.1550	n-heptane, 2 hours	<0.003	0.03	PASS
FDA 177.1550	ethyl acetate, 2 hours	<0.003	0.03	PASS

* Maximum acceptable migration according to FDA 177.1550

Overall migration results of <u>total extracts</u> into food simulant on FC050 material samples (mg/inch ²)				
FDA test method	Reflux test conditions	Result	Limit*	Conclusion
FDA 177.1550	distilled water, 2 hours	<0.05	0.20	PASS
FDA 177.1550	ethanol 50%, 2 hours	<0.05	0.20	PASS
FDA 177.1550	n-heptane, 2 hours	<0.05	0.20	PASS
FDA 177.1550	ethyl acetate, 2 hours	<0.05	0.20	PASS

* Maximum acceptable migration according to FDA 177.1550

Overall migration into <u>aqueous food</u> simulants on FC050 material samples (mg/dm ²)				
According to reference standard CE 1935/2004 + Reg (EU) 10/2001				
Simulant	Reflux test conditions	Mean over 3 samples	Limit	Conclusion
(B) 3% acetic acid	4 hours (repeated use)	<1	10	PASS
(D1) ethanol 50%	4 hours (repeated use)	<1	10	PASS

Since the article is intended to come into repeated contact with foods, the migration tests were carried out three times on each single test sample using another portion of food simulant on each occasion and compliance has been checked on the basis of the level of migration found at the end of the third test.

Overall migration into <u>fatty food</u> simulants on FC050 material samples (mg/dm ²)				
According to reference standard CE 1935/2004 + Reg (EU) 10/2011				
Simulant	Reflux test conditions	Result	Limit*	Conclusion
(D2) vegetable oil	2 hours @ 175°C	<2	10	PASS

Since the article is intended to come into repeated contact with foods, the compliance has been checked on the basis of the level of migration resulting from the difference between mean result found in the third test and the result found in the second test.

European legislation:

According to the declarations of compliance to food contact legislations, this material contains the substance mentioned in the table below and has restrictions in accordance with the above mentioned legislation.

Determination of residual content of Tetrafluoroethylene (CAS No. 116-14-13) (mg/kg)					
According to reference standard CE 1935/2004 + Reg (EU) 10/2011					
Weight of material	Content (mg/kg)	Content (mg/dm ²)	Theoretical migration ⁽¹⁾	Specific migration Limit*	Conclusion
43.8 (g/dm ²)	<0.01	<0.01	<0.003	0.05	Below limit

⁽¹⁾ It is assumed that the whole content (100%) of the compound migrates taking into account the conventional exposure factor of 6 (dm)² / (kg)

* Limit as defined in Annex 1 of EU regulation 10/2011

We hereby declare that the material complies with the following Chinese regulations:

GB 4806.1 - 2016 - "General safety requirements on Food Contact Materials and their products"

GB 4806.6 - 2016 - "Food contact plastic resins"

GB 4806.7 - 2016 - "Plastic Materials and Articles in Contact with Foodstuffs"

GB 9685 - 2016 - "Hygienic Standards for uses of additives in food containers and packaging materials"

GB 5009.156-2016 - "General principle of migration test pre-treatment method of food contact materials and their products"

GB 31604.1 - 2015 - "General rules for migration test of food contact materials and products"

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