3M Separation & Purification Sciences Division

LifeASSURE™ PFS SERIES FILTER CARTRIDGES

Declaration of Compliance for Food Contact

This document is the declaration of compliance within the meaning of Article 16(1) of Regulation (EC) No. 1935/2004.

1) Manufacturer

3M Purification Inc, 400 Research Parkway, Meriden, CT 06450, USA

2) Product Descriptions Covered by this Document

LifeASSURE™ PFS Series Cartridges

Type	Configuration	Height (Inches)	End Modification	O-ring Material
PFS020	A	25 – 2.5 50 – 5 01 – 10 02 – 20 03 – 30 04 – 40	B – 226 O-ring & spear C – 222 O-ring & spear F – 222 O-ring & flat cap J – 226 O-ring & flat cap	A – Silicone B – Fluorocarbon C – EPR D – Nitrile

LifeASSURE™ PFS Series Mini Cartridges

Type	Configuration	Height (Inches)	End Modification	Package Quantity
PFS020	R	01 – 2.5 02 – 5	AN	06 – 6 per pack

3) Composition

Membrane	PTFE
Support layer	Polypropylene
Core, cage	Polypropylene
End modifications	Polypropylene
Support Ring	Stainless steel
O-Rings/Gaskets	As ‘Product Description’ table above

4) Compliance with Regulation (EC) 1935/2004

Hereby we declare the product(s) comply with the legal requirements as laid down in Regulation (EC) 1935/2004 as amended.

They are manufactured from materials that are suitable for contact with foodstuffs according to the following European specific measures or other recognized standards where specific measures have yet to be defined;

Plastic Parts

The plastic components of the product have been manufactured only with authorised monomers, other starting substances, additives and polymer production aids that are listed in Annex I of Regulation (EC) 10/2011 as amended. Migration testing according to Article 17 and 18 of Regulation (EC) 10/2011 as amended in conjunction with Annex V shows that when used as specified the overall migration is below 10 mg/dm^2.

The product may contain the following substances that are subject to a specific migration limit (SML).

Substance	CAS#	SML/QM/QMA
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	6 mg/kg
Bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	26741-53-7	0.6 mg/kg
1-(2-hydroxyethyl)-4-hydroxy- 2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	65447-77-0	30mg/kg
Tetrafluoroethylene	116-14-3	0.05 mg/kg

Migration testing according to Article 17 and 18 of Regulation (EC) 10/2011 as amended in conjunction with Annex V shows that when used as specified the specific migration is below the allowed limits.

The product may contain the following substances that are also approved as food additives, dual use additives.

E470A Calcium salt of fatty acid

The product may contain the following non-intentionally added substances (NIAS).

Polyolefin materials may contain trace levels of phthalates as impurities. According to information from 3M Purification's suppliers the maximum amount of these phthalate impurities in their product is 15ppm in total but typically much less. Specific migration testing of several similar products has shown these phthalates to be non-detectable.

There is no functional barrier present.

Metal Parts

The optional metal support ring is made from a food grade stainless steel; EN 1.4404 (316L), that is compliant with the compositional requirements of the French order of 13th January 1976.

Rubber Parts

In the absence of any European harmonized standard compliance for the rubber O-rings is based upon the following standards:

FDA CFR21

Silicone	177.2600	Aqueous, acidic, alcoholic and dairy applications.
Fluorocarbon	177.2600	Aqueous, acidic, alcoholic and dairy applications.
EPR	177.2600	Aqueous, acidic, alcoholic applications only.
Nitrile	177.2600	Aqueous, acidic, alcoholic applications only.

Conditions of Use

Food types: All aqueous, acidic and alcoholic (max 50%) and dairy foods. (Note: Products with nitrile and EPR o-ring options aqueous, acidic, alcoholic only)

Contact time and temperature: The product is intended to be used at room temperature or below under flow conditions. Migration testing was carried out according to OM3 allowing any food contact conditions that include hot-fill and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for maximum of t = 120/2^((T-70)/10) minutes, which are not followed by long term room temperature or refrigerated storage.

Ratio of food contact surface area to volume used to establish compliance: Due to the complex nature of the product and intended application it is impracticable to estimate the relationship between the surface area of such articles and the quantity of food in contact therewith. Migration testing was conducted on representative samples of the individual components and a surface to volume ratio 6dm^2 to 1kg applied.

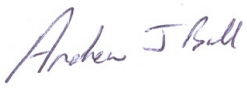
5) Good Manufacturing Practice

The product(s) are manufactured at an ISO 9001:2008 certified facility in accordance with good manufacturing practice as required by Regulation (EC) No.2023/2006. The product(s) have fully documented traceability throughout the manufacturing process that is identifiable by the means of a lot number printed on the product label or quality documentation supplied with the product.

The information provided in this document related to material content represents 3M Purification's knowledge and belief as of the date it is provided which may be based in whole or in part on information provided by suppliers to 3M.

In the event any Product is proven not to conform with 3M's certification, then to the extent permitted by law, 3M's entire liability and Buyer's exclusive remedy, will be at 3M's option either: (i) replacement of Product with a conforming product, or (ii) refund of the purchase price paid by Buyer for each non-conforming Product, within a reasonable time after written notification of said non-conformance and return of said Product to 3M. 3M shall not under any circumstances be liable for direct, incidental, special, or consequential damages (including but not limited to loss of profits, revenue, or business) related to or arising out of this certification, including, the use, misuse or inability to use the Product. Unless stated otherwise in writing, the foregoing language cannot be waived, modified, or supplemented in any manner whatsoever.

Certified by:



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Date Issued: 23rd November 2020
This document remains valid for a period of 1 year from the date of issue.