



# LifeASSURE™ BLA 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

Type	Removal Rating (µm)	Configuration	Length (Inches)	End Modification	O-ring Material	Support Ring
BLA	020 – 0.20 045 – 0.45 065 – 0.65 080 – 0.80	B – Pleated APT material	01 – 10 02 – 20 03 – 30 04 – 40	B – 226 O-ring & spear C – 222 O-ring & spear D – Double open end (10") E – Double open end (9.75") F – 222 O-ring & flat cap J – 226 O-ring & flat cap	A – Silicone B – Fluorocarbon C – EPR D – Nitrile H – Clear silicone	Blank PSF  2 Stainless steel

### 3) Composition

Filter Membrane	Polyamide
Filter Membrane	Polypropylene/Polyethylene
Support layer	Polypropylene
Core, cage	Polypropylene
End modifications	Polypropylene
Support Ring	Polysulphone/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. Migration testing according to Article 17 and 18 of Regulation (EC) 10/2011 in conjunction with Annex V shows that when used as specified the overall migration is below 10 mg/dm<sup>2</sup>.

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
Hexamethylenediamine	124-09-4	2.4mg/kg
Distearyl thiodipropionate	693-36-7	5 mg/kg
Bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphate	26741-53-7	0.6 mg/kg
2,6-Di-tert-butyl-p-cresol(BHT)	128-37-0	3 mg/kg
1,3,5-Tris(3,5-di-tert-butyl-4 hydroxybenzyl) 1,3,5-triazine-2,4,6(1H,3H,5H)trione	27676-62-6	5 mg/kg
1-(2-hydroxyethyl)-4-hydroxy- 2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	65447-77-0	30mg/kg
Bisphenol A*	80-05-7	0.6 mg/kg
4,4-Dichlorodiphenylsulfone*	80-07-9	0,05 mg/kg
Zinc Oxide*	1314-13-2	25 mg/kg

\* Only present in products with optional polysulphone support ring.

Migration testing according to Article 17 and 18 of Regulation (EC) 10/2011 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 – all components are in conformance with the requirements for food contact in the FDA CFR21 (see section 6).

USP <88> Class VI Biological Reactivity Tests for Plastics - All O-ring materials used in this product meet the requirements of the USP guidelines for plastics Class VI.

### Conditions of Use

Food types: All aqueous, acidic and alcoholic foods and milk products.

Contact time and temperature: The product is intended to be used at 70°C or below under flow conditions.

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 a complete filter cartridge and a surface to volume ratio of 6 dm<sup>2</sup>/kg is 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.

## **6) FDA CFR21**

All materials of construction are listed for food contact in the FDA CFR Title 21 as follows;

Polyamide	177.1500
Polypropylene	177.1520
Polyethylene	177.1520
Polysulphone	177.1655
Stainless Steel	GRAS
Silicone	177.2600
Fluorocarbon	177.2600
EPR	177.2600
Nitrile	177.2600

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

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Certified by:



**Andrew J Ball**  
**Product Responsibility Liaison I&TB**

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This document remains valid for a period of 1 year from the date of issue.