



## Betapure™ NT-TE 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 Wroclaw Sp. z o.o. ul. Kowalska 143, PL-51-424 Wroclaw, Poland

#### 2) Product Descriptions Covered by this Document

Type	Length (in)	Grade Code/Rating (µm)	Packaging Option	Support Ring Option	End Modification	O-ring Material
NT	06 - 5 09 - 9.75 10 - 10 19 - 19.5 20 - 20 29 - 29.25 30 - 30 39 - 39 40 - 40	T005 - 0.5 T010 - 1 T020 - 2.5 T030 - 3 T050 - 5 T100 - 10 T200 - 20 T300 - 30 T400 - 40 T500 - 50 T700 - 70	S Z	0 - None 1 - Polysulphone 2 - Stainless Steel	B - 226 O-ring & spear C - 222 O-ring & spear D - DOE with end caps F - 222 O-ring & flat cap N - Unmodified DOE P - Polypropylene core extender Q - SOE, End cap without spring R - SOE End cap with spring Y - Single O-ring	A - Silicone B - Fluorocarbon C - EPR D - Nitrile G - Polyethylene

#### 3) Composition

Media	Polypropylene
Netting	Polypropylene
Core	Polypropylene
End modifications	Polypropylene
Support Ring (Optional)	Polysulphone or stainless steel
O-Rings/Gaskets	As 'Product Description' table above
Spring	Stainless Steel

#### 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
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 and spring are 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 room temperature or below under flow conditions (contact time of < 24 hrs).

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;

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

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:



**Andrew J Ball**

**Product Responsibility Liaison I&TB**

3M United Kingdom PLC  
Tech Centre  
Ratcliffe Rd, Warwickshire,  
CV9 1PJ, UK

Tel: +44 (0)1827 710320  
Fax: +44 (0)1827 710393  
Email: aball5@mmm.com

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