



# Betapure™ NT-P SERIES FILTER CARTRIDGES

## Product EHS & Regulatory Information

This document provides basic information with regard to the compliance of the above product with various regulatory and industry standards. For other product information or if you have questions regarding regulations or standards not covered in this document please contact 3M Purification.

### 1) Manufacturer

3M Purification, 3M Poland Sp. z o. o., Al. Katowicka 117, 05-830 Nadarzyn

### 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	P005 - 0.5 P010 - 1 P020 - 2.5 P030 - 3 P050 - 5 P100 - 10 P200 - 20 P300 - 30 P400 - 40 P500 - 50 P700 - 70	Z	0 - None 1 - Polysulphone 2 - Stainless Steel	B - 226 O-ring & spear, C - 222 O-ring & spear F - 222 O-ring & flat cap M - 222 O-ring & flat cap Y - Single O-ring	A - Silicone B - Fluorocarbon C - EPR D - Nitrile K - PTFE Encapsulated fluorocarbon

### 3) Composition

Media	Polypropylene
Netting	Polypropylene
Core	Polypropylene
End modifications	Polypropylene
Support Ring	Polysulphone or stainless steel
O-Rings/Gaskets	As 'Product Description' table above

## 4) Compliance with Regulatory and Industry Standards

### MSDS

This product is defined as an article under REACH and does not require a Safety Data Sheet under Article 31 of Regulation (EC) No. 1907/2006.

### Food Contact - Regulation (EC) 1935/2004

Betapure™ NT-P Series filter cartridges comply with the requirements of Regulation (EC) 1935/2004 in that; plastic materials comply with Regulation (EC) 10/2011, all monomers and additives are listed in Annex I and migration testing in simulants B (3% acetic acid) and C (50% ethanol) has shown that total and specific migration limits will not be exceeded under normal conditions of use. Non-plastic materials if present comply with other recognized standards. A full declaration of compliance is available, contact 3M Purification for details.

### 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
Nitrile	177.2600
PTFE	177.1550
Polyethylene	177.1520

### USP<88> Class VI Biological Reactivity Tests for Plastics

Representative samples of Betapure™ NT-P Series filter cartridges have been tested and found to meet the requirements of the USP guidelines for plastics Class VI – 70°C.

### MEM Elution Cytotoxicity Testing

Representative samples of Betapure™ NT-P Series filter cartridges have been tested and found to meet the requirements of the USP 23 Elution test and are considered non-cytotoxic.

### Animal Derived Products (BSE/TSE)

3M Purification understands the continued public interest and the increased regulatory scrutiny concerning the transmission of bovine spongiform encephalopathy (BSE) and other transmissible spongiform encephalopathies (TSE). In order to address these issues, the following statement is offered:

Animal or animal derived materials are not used directly in our manufacturing processes. In order to assess the BSE/TSE risk associated with the Betapure™ NT- P Series filter cartridges, we have contacted our suppliers of raw materials and performed an evaluation of our production processes to determine if any of the materials used are of animal origin. The result of our survey and inquiries of our raw material suppliers has revealed that the polypropylene resins used to mould parts may contain tallow derivatives and certain rubber gaskets could contain a stearic acid that is used as an activator in the vulcanization process. We can state, however, that these parts which use tallow derivatives and stearic acid are processed at conditions conforming to the requirements of the European Agency for the Evaluation of Medicinal Products EMEA/410/01 rev. 3 and are thought unlikely to be infectious, per said regulation.

**Regulation (EC) 1907/2006 REACH:**

Betapure™ NT-P Series filter cartridges are articles with no intended release of a chemical substance, under the REACH regulation (Article 3(3)) and are therefore not subject to pre-registration or registration requirements.

With regard to Substances of Very High Concern (SVHC) to the best of 3M's knowledge, the chemicals from the Candidate List as amended on 17<sup>th</sup> December 2014 are not present at or above 0.1%.

The cartridges as supplied by 3M are not considered to be dangerous within the meaning of Article 2 of Directive 67/548/EEC and its amendments or Article 2 of Directive 1999/45/EC. Therefore they are not within the scope of Regulation (EC) 1907/2006 Article 31 requiring the provision of a safety data sheet.

**Directive 2011/65/EC 'RoHS'**

Betapure™ NT-P Series filter cartridges are not electrical and do not rely on electrical currents or electromagnetic fields to operate, they are therefore not in scope of this directive. However to the best of 3M's knowledge the product does not contain any of the listed substances in excess of the maximum concentration values in the Directive,

**Allergens**

Betapure™ NT-P Series filter cartridges do not knowingly contain any allergens as defined by Annex IIIa of European Directive 2000/13/EC as amended by Directive 2007/68/EC.

**Genetically Modified Organisms (GMOs)**

Betapure™ NT-P Series filter cartridges do not knowingly contain any GMOs as defined by Article 2(2) of European Directive 2001/18/EC.

**Phthalates**

3M Purification does not use phthalate plasticisers in the manufacture of Betapure™ NT-P Series filter cartridges including;

Di-n-butyl phthalate (DBP)	CAS 84-74-2
Di (2-ethylhexyl) phthalate (DEHP/DOP)	CAS 117-81-7
Di-isodecyl phthalate (DIDP)	CAS 26761-40-0
Di-n-hexyl phthalate (DNHP)	CAS 84-75-3
Di-Isononyl phthalate (DINP)	CAS 28553-12-0
Di-isobutyl phthalate (DIBP)	CAS 84-69-5
Butyl benzyl phthalate (BBP)	CAS 85-68-7
Dipentyl phthalate (DPP)	CAS 131-18-0

One raw material used in the construction of the Betapure™ NT-P Series filter cartridges may contain trace amounts of phthalates as an impurity at a level of 10 – 15 ppm. Di (2-ethylhexyl) phthalate (DEHP/DOP) may be present in small amounts (<0.1%) in products using the nitrile 'D' O-ring.

**Bisphenol A (BPA)**

3M Purification does not use BPA in the manufacture of Betapure™ NT-P Series filter cartridges and it is not known to be present except for products that include the optional polysulphone support ring e.g.NTxxPxxxx1xx. BPA is known to be a starting material for polysulphone,

migration testing of the polysulphone support ring in accordance with Regulation 10/2011 in 3% acetic acid and 50% ethanol under conditions of 24 hrs at 40°C has shown BPA to be not detectable at a detection limit of 0.06 mg/kg.

#### **Latex**

3M Purification does not use natural rubber latex in the manufacture of Betapure™ NT-P Series filter cartridges and it is not known to be present.

#### **Aflatoxins/Mycotoxins**

Betapure™ NT-P Series filter cartridges are not intended for human consumption and are manufactured from materials that would not be considered as sources of aflatoxins/mycotoxins. Therefore aflatoxins/mycotoxins are not known to be present in the products as supplied however 3M does not test for the presence of aflatoxins/mycotoxins.

#### **Ionising Radiation**

Betapure™ NT-P Series filter cartridges do not undergo ionizing radiation treatment.

#### **Nanotechnology**

Betapure™ NT-P Series filter cartridges do not knowingly incorporate nanotechnology, defined as the application of engineered structures at the nanoscale (<100nm).

**Disclaimers:** The information provided in this document related to material content represents 3M Purification's knowledge and belief, which may be based in whole or in part on information provided by suppliers to 3M. This is intended to answer commonly asked questions about 3M Purification products and is not intended to be a comprehensive listing of all substances that may be of interest or that may be regulated in this or other 3M products, nor is it intended to be a comprehensive summary of any and all regulations that may apply to this product. Where substances are listed, their listing does not infer or constitute a judgment as to their safety, environmental or health impacts. Information is supplied upon the condition that the persons receiving the same will make their own determination as to its suitability for their purpose prior to use. Customers are encouraged to consult with legal and regulatory experts to determine applicable regulations in light of intended use of the product.

**Limitation of Remedies and Liability:** 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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