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 17th 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.NTxxPxxxx**1**xx. 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 40ºC 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).

Certified by:

Andrew J Ball
Product Responsibility Liaison I&TB

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