# Betafine<sup>™</sup> XL 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 Inc, 400 Research Parkway, Meriden, CT 06450, USA

# 2) Product Descriptions Covered by this Document

Туре	Length (in)	Material	Grade Code/Rating (μm)	End Modification	O-ring Material
XL	$\begin{array}{rrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrr$	PP - Polypropylene	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	B0 – 226 O-ring & spear, no reinforcing ring B1 – 226 O-ring & spear, polysulphone ring B2 – 226 O-ring & spear, stainless steel ring C0 – 222 O-ring & spear, no reinforcing ring C1 – 222 O-ring & spear, polysulphone ring C2 – 222 O-ring & spear, stainless steel ring F0 – 222 O-ring & flat cap, no reinforcing ring F1 – 222 O-ring & flat cap, polysulphone ring F2 – 222 O-ring & flat cap, stainless steel ring D – Double open end R – Single open end with steel spring	A – Silicone B – Fluorocarbon C – EPR D – Nitrile K – PTFE Encapsulated fluorocarbon G – Polyethylene

# 3) Composition

Media	Polypropylene
Support layer	Polypropylene
Core, cage, end caps	Polypropylene
End modifications	Polypropylene
Support Ring	Polysulphone or stainless steel
O-Rings/Gaskets	As 'Product Description' table above
Spring	Steel

# 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

Betafine<sup>™</sup> XL 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 Betafine<sup>™</sup> XL Series filter cartridges have been tested and found to meet the requirements of the USP guidelines for plastics Class VI – 121°C.

## 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 Betafine<sup>TM</sup> XL 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:

Betafine<sup>™</sup> XL 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'

Betafine<sup>™</sup> XL 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

Betafine<sup>™</sup> XL 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)**

Betafine<sup>™</sup> XL 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 Betafine<sup>™</sup> XL Series 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

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 Betafine<sup>™</sup> XL Series filter cartridges and it is not known to be present except for products that include the optional polysulphone support ring. 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 Betafine<sup>™</sup> XL Series filter cartridges and it is not known to be present.

#### Aflatoxins/Mycotoxins

Betafine<sup>™</sup> XL 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**

Betafine<sup>™</sup> XL Series filter cartridges do not undergo ionizing radiation treatment.

## Nanotechnology

Betafine<sup>™</sup> XL 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.

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Certified by:

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