



TECHNICAL PUBLICATION  
REGULATORY COMPLIANCE OF  
AMAZON'S FILTER CARTRIDGES  
FOR FOOD AND BEVERAGE  
APPLICATIONS

TP0024



### Regulatory Compliance of Amazon Filters' Cartridges Designed for Food and Beverage Applications

Filter cartridges used for critical filtration applications in the Food and Beverage industries must conform to strictly defined manufacturing and quality standards. This Technical Publications describes to relevant USA and European standards that Amazon Filters comply with, assuring they can be safely used for the manufacture of Food and Beverage products. These standards generally apply to Amazon's **SupaPore VPWS, VWA, VPW, TPB** membrane filter ranges, **SupaPore PPG, FPW** and **SupaPleat** ranges of pleated depth filters and **SupaSpun, SupaGard** and **Contour** ranges of meltblown depth filters.



### Quality Assurance and Manufacturing Environment

Amazon Filters operate a well-established Quality Assurance System, which is accredited to BS EN ISO 9001:2008 by the British Standard Institute (Certificate No. 39584) with full design and manufacturing approval.

Filters are manufactured in a facility and using processes that have been regularly audited. They have been shown to be in compliance with current GMP requirements for suppliers of disposable product contact items to the pharmaceutical and food industries as laid down by the US Food and Drugs Administration (FDA) (specifically with the relevant parts within 21CFR), the European Medicines Agency (EMA) and the Food Regulations relating to the European Community.

Filter cartridges are manufactured in a controlled cleanroom environment using well defined and documented work instructions and quality plans, thus ensuring that the highest quality and cleanliness standards are consistently maintained. Our Quality Assurance System assures full product traceability.

### Food Contact Compliance

#### US FDA CFR Title 21 for Food Contact

All the materials used in the construction of Amazon's filter cartridges fulfil the requirements on materials used for articles intended to come into contact with food as described in US **FDA CFR Title 21 (Section 177)**.

Amazon's membrane filter cartridges comply with the United States FDA Title 21 CFR sections 210.3(b)(6) and 211.72, relating to non-fibre releasing filters.

### EC Food Contact Compliance

Amazon Filters ranges of filter cartridges designed for the Food and Beverage industries meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

They have been assessed by an external laboratory under the Plastics Materials and Articles in Contact with Foodstuffs Regulations laid out in EC Directive 2002/72/EC and its amendments to present date (EC Directives 2004/1/EC, 2004/19/EC, 2005/79/EC & 2007/19/EC).

All substances identified as being used in the manufacture of the above products are (a) listed in the above legislation, or (b) not subject to the provisions of the above legislation.



Tests have shown that the above product family will meet the global migration limits into liquid types A, B & C (aqueous, acidic and alcoholic products) when tested under repeat-use test conditions.

The materials in construction of this product family are not subject to the provisions of EC Regulation 1895(2005) and do not use BADGE, BFDGE or NOGE.

Additionally, Amazon Filters Ltd declares that its quality & manufacturing system meets the requirements of EC Regulation 2023(2006) 'The good manufacturing practice Regulation' for food contact materials.

### Plasticizers & Phthalates

Amazon Filters Ltd does not use in the manufacture or intentionally add plasticizers or phthalates to its range of cartridge filters. However, based upon information from the raw material suppliers, the polypropylene resins used may typically contain trace amounts of phthalates as a result of residual catalyst components. These trace levels of phthalates are typically at very low ppm levels.

All packaging materials used in direct contact with Amazon Filters' cartridges are made from raw materials that do not contain Silicones, Amines or Phthalates, and these chemicals are not knowingly used in the production processes. The packaging is therefore classed as SAP free.

### Statement on Polymer Additives & BSE

Amazon's cartridge filters are considered highly unlikely to present a risk of TSE/BSE transmission. Our products are considered to be in compliance with the European 'Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/01 REV. 2 - October 2003) adopted by the Committee for Proprietary Medicinal Products (CPMP) and by the Committee for Proprietary Veterinary Products (CPVP).

In addition we certify that they are unlikely to pose a risk for TSE infectivity according to the USP Perspective to Minimize the Potential Risk of TSE Infectivity in Bovine-Derived Articles Used in the Manufacture of Medicinal Products, *USP Pharmacopeial Forum*, Vol. 30(5), Sept-October 2004.

Our suppliers state that the polymers used in the manufacture of the above filters may incorporate small amounts of tallow based additives, stearates or other materials that are derived from fatty acids and during processing, a re-esterification or hydrolysis process is used with a minimum temperature of 200°C and an appropriate pressure for at least 20 minutes. Subsequent processing at the granulation and fibre production stages takes place at temperatures in excess of 200°C for several minutes. This fulfils the requirements laid down in the Notes For Guidance, EMEA.410/01 Rev.2.

Animal derived materials are not intentionally used during the manufacture of the raw material used in the seals fitted to Amazon's filter cartridges.

### Amazon Range of Filter Cartridges for the Food and Beverage Industries

Amazon supplies **SupaPore VPWS, VWA, VPW, TPB** membrane filter ranges, **SupaPore PPG, FPW and SupaPleat** ranges of pleated depth filters and **SupaSpun, SupaGard and Contour** ranges of meltblown depth filters to the Food and Beverage industries. Due to the different materials and manufacturing techniques used in these different ranges of filters there may be exceptions to the general standards detailed above. Therefore users are advised to refer to the individual Product Validation Guides for confirmation that these standards apply to the Amazon filter being used.



## AMAZON FILTERS LTD.

Albany Park Estate  
Frimley Road, Camberley  
Surrey, GU16 7PG  
England

Tel: +44 (0) 1276 670 600  
Fax: +44 (0) 1276 670 101  
Email: [Sales@amazonfilters.co.uk](mailto:Sales@amazonfilters.co.uk)  
Web: [www.amazonfilters.com](http://www.amazonfilters.com)