Ultradyne[®]

0.2 µm TM-grade 50 mm Capsule Filter (CB2 Model)

Description

The Ultradyne[®] TM0.2 is a hydrophobic PTFE membrane filter optimized for small-scale gas line and air venting applications. Designed for bidirectional flow, this filter is well suited for applications requiring high efficiency removal of airborne bacteria and particulates from air and gas streams, such as fermenter inlet air and exhaust, process air, and sterile venting of carboys, filling vessels, bioreactors and small product or intermediate tanks. The product also has broad chemical compatibility and is suitable for filtering aggressive solvents.

Materials of Construction

All components of the encapsulated discs are animal component free (ACF). These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Membrane: Downstream support: Capsule housing: Sealing method:	Polytetrafluoroethylene Polypropylene Polypropylene Thermal bonding	CFR Title 21, 177.1550 CFR Title 21, 177.1520 CFR Title 21, 177.1520
Pore Size	0.2 μm	
EFA	19.6 cm ²	
Minimum Bubble Point	14 psi (0.96 bar) 60% IPA/40% water	
<i>Operating Characteristics</i> Operating temperature range: Maximum temperature rating: Maximum operating pressure: Maximum reverse pressure:	32 °F to 100 °F (0 °C to 38 °C) 160 °F @ 35 psig (71 °C @ 2.4 b 80 psig (5.5 bar @ 38 °C) 15 psig @ 100 °F (1.0 bar @ 38	,

Sterilization

Autoclave: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, \ge 3 cycles. Capsules must not be in-line steam sterilized. Gamma irradiation is not recommended.

Biological Safety

Ultradyne[®] filters meet the requirements as specified in the current USP <88> Class VI plastics, and USP <87> cytotoxicity tests, and pyrogenicity tests. No adhesives, binders or surfactants are used in the construction of the filters. Filters comply with European Commission Regulation No 10/2011. The 50 mm capsules are TSE/BSE/animal component free (ACF).

Quality Assurance

Ultradyne[®] filters comply with the Food and Drug Administration Code of Federal Regulations, Title 21, Parts 210 and 211. Product is manufactured and packaged in a cleanroom facility that, through voluntary compliance, meets or exceeds FDA Good Manufacturing Practice Standards. To ensure product reliability, Meissner's Quality Assurance staff continually audits the manufacturing process for conformance to its Quality Management System. Each Ultradyne[®] filter is clearly marked with filter type and lot number.



Ordering Guide



Additional information about this filter product is available in the Ultradyne® Green Docs document at www.meissner.com/green-docs.

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