

Catalog Number: 431474

Product Description: Corning® 1 L filter system, polyethersulfone (PES) membrane, 0.1 µm pore size

Component Materials:

- Funnel, Funnel Lid & Receiver/Storage Bottle - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- Funnel Adapter, Hose Connector & Plug - Virgin High Density Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.
- Seal Cap - Polyethersulfone (PES), 0.1 µm pore size
- Membrane - Polyethersulfone (PES), 0.1 µm pore size
- Gasket - Polyethylene Foam liner
- Adapter Plug - Cellulose Acetate

Sterilization:

The product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization*.

Sterility Assurance Level: SAL 10⁻⁵

Pyrogens:

The product has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72: *Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing*. Results: less than 0.1EU/mL.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest revision of EMEA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

Membrane Bacterial Retention:

The product has been tested as per the HIMA guidelines and determined to be quantitatively retentive at a concentration of 10⁷ organisms per cm² using *Brevundimonas diminuta*.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Membrane Integrity Test: Forward pressurization of the membrane seal to the funnel.

Visual Attributes: Visual examination of the product.

Packaging: Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

Revision Date:

05-04-20

Rev No: 5