Quality Certificate

VWR® VACUUM FILTRATION SYSTEMS FEATURING PALL MEMBRANES

As per the manufacturer, the below product meets the following criteria:

North American Catalog No:	97066-204
Manufacture Lot Number:	34717830
Description:	VWR LAB FILTRATION 1000ML ASSEMBLY
Date of Manufacture:	June 2019
Date of Sterilization:	July 12, 2019
Sterilization Expiration Date:	July 2024
Country of Origin:	North America
Country of Sterilization:	USA

Quality System Compliance

Good Manufacturing Practice: This product was manufactured in a Class 100,000 clean room facility that is certified to ISO 13485 Device manufacturing.
ISO 13485 Quality Standard: This product was manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 13485 Quality Systems Standard.

Quality Testing

Representative production samples are collected and inspected in accordance with current applicable product specifications.

Product Specifications

Material:

- **Filter Housing, Bottle, Lid**- Polystyrene;
- **Membrane**- Polyethersulfone (PES);
- **Cap, Vacuum Adapter**- Polypropylene.

Component Material Toxicity: All component materials have been tested and meet the requirements for United States Pharmacopoeia (USP) class VI Biological Test for Plastics, current edition. The plastics meet the requirements of the United States Food and Drug Administration (FDA) for food and beverage contact in 21 CFR 177.1640.

Maximum Operating Vacuum: 20 in Hg (51 cm) Hg (15 in Hg (38 cm) Hg recommended)

Temperature Range:
- Operating Range: 39º to 98ºF (4º to 37ºC)
- Unit Storage: -20º to122ºF (-4º to 50ºC)

Flammability: UL94 flame rating

Audit Criteria: Audit criteria tests are conducted to determine the viable microbial bioburden of the product.

Sterilization Dose Audit: Gamma irradiation dose is audited on a quarterly basis.

Sterilization Procedure: Individually bagged and sterilized by gamma irradiation VDMax 10^{-6} in the USA.

Quality Certificate

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Membrane Bubble Point: Each membrane pore size was certified according to a procedure established by the manufacturer to determine the water bubble point.

- 0.22 µm Pore Size: 62.4 psi (4.3 Bar)
- 0.45 µm Pore Size: 43.5 psi (3.0 Bar)

Bacterial Retention:

- 0.2 micron membrane samples were quantitatively retentive of a minimum Brevundimonas diminuta challenge concentration of 1x 10^{-7} cfu per cm^2 using ASTM methodology.
- 0.45 micron membrane samples were quantitatively retentive of a minimum S. marcescens challenge concentration of 1x 10^{-7} cfu per cm^2 using ASTM methodology.

BPA Statement:

- ***Filter Housing, Bottle, Lid (Polystyrene)*** - Bisphenol A is not used in the manufacture of or the formulation of this product. However, this product has not been tested for this chemical substance.

- ***Cap and Vacuum Adapter (Polypropylene)*** - Bisphenol A is not used in the manufacture of or the formulation of this product. However, this product has not been tested for this chemical substance.

DEHP Statement:

Filter Housing, Bottle, Lid (Polystyrene)

- Phthalates are not deliberately added to the product. This includes di (2-ethylhexyl) phthalate (DEHP; CAS# 117-81-7), di butyl phthalate (DBP; CAS# 84-74-2), benzyl butyl phthalate (BBP; CAS# 85-68-7), diisononyl phthalate (DINP; CAS# 71549-78-5), diisodecyl phthalate (DIDP; CAS# 26761-40-0), and di-n-octyl phthalate (DNOP; CAS # 117-84-6).

Cap and Vacuum Adapter (Polystyrene)

- Phthalate plasticizers are in general used in specific non-olefinic resin systems to soften these resins and make them flexible. When phthalate plasticizers are added, they can constitute up to 50% of the resultant plastic material. Polyolefins do not require the use of plasticizers to make them soft and flexible. No phthalates plasticizers, such as di(2-ethylhexyl) phthalate (DEHP) or di-octyl phthalate (DOP) [CAS# 117-81-7], di-iso-nonyl phthalate (DINP) [CAS# 28553-12-0], di-iso-decyl phthalate (DIDP) [CAS# 26761-40-0], di-butyl phthalate (DBP) or di-n-butyl phthalate (DNBP) [CAS# 84-74-2], butyl benzyl phthalate (BBP) [CAS# 85-68-7] and di-n-octyl phthalate (DNOP) [CAS# 117-84-0], are intentionally used in the formulation of this product. However, a phthalate compound, diisobutyl phthalate (DIBP) [CAS# 84-69-5], is used in the manufacturing process as a “technical support agent” (as defined by the European Union), i.e. a minor component of the catalyst system. This is typical of polypropylene and polybutene resins produced with high mileage catalysts. Impurities in the “technical support agent” and catalyst system include DBP (or DNBP), DEHP (or DOP), diethyl phthalate (DEP) [CAS# 84-66-2] and isobutyl ethyl phthalate (IBEP) [CAS# 94491-96-0]. Testing of several resins has resulted in the identification of the overall residual phthalate content no more than 10-15 parts per million. Further testing with food simulants (per EU Regulation 10/2011/EC) has resulted in phthalates not detected at a sensitivity of 20 parts per billion (0.02 parts per million). To put these results in perspective, plastic materials that require phthalate plasticizers

BSE/TSE Statement:

Filter Housing, Bottle, Lid (Polystyrene)

- The monomers used in the manufacture of these products are of petrochemical origin and not from cattle, sheep, or goat. All raw materials used are either not manufactured from animal derived substances, or if animal-derived are from animal material that originates in the United States or Canada from bovine or porcine material (specifically, no bovine or porcine material from countries whose animals are known to be infected with BSE or TSE is used in the production). Further, any animal-derived additives are treated under conditions involving heating at 200°C at 40 bar pressure for three or more hours followed by vapour phase distillation.

Quality Certificate

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Cap and Vacuum Adapter (Polystyrene)

- One additive in this product is derived from animal sources. Our suppliers have stated that their additive is derived from bovine material. They have assured us that the animal material is sourced from the United States, Canada or Mexico. The bovine material can be any part of the animal. There were two sets of process conditions specified by our suppliers for processing the bovine material. These are: (1) Hydrogenation of tallow @200 deg. C, hydrolysis @260 deg. C, and 48 bar for 1.5-2 hours and vacuum distillation @232 deg. C; (2) Hydrolysis of tallow @260 deg. C and 700 psig for 3 hours, hydrogenation of stearic acid @232 deg. C and 300 psig for 2.5 hours, and distilled at 232 deg. C for 5 minutes.

Pyrogen Statement: An aqueous extraction from the unit contains less than 20 EU/device as determined using the Limulus Amebocyte Lysate (LAL) test.

Cytotoxicity Statement: Plastic component materials are non-cytotoxic and meet the Elution Test 10993-5, 1999.

Latex Statement: Product is Latex-Free.

Signed:

Jamie Ethier
VP Global Quality
VWR, Part of Avantor

Date: January 17, 2020