PALL Food and Beverage

DECLARATION OF COMPLIANCE
Fuente Filter Cartridges
AB Style “W” Code

Cartridge Part Number

AB [ ] FF [ ] W [ ] [ ]
Table 1 Table 2 Table 3 Table 4

This is a guide to the Part Numbering structure only. For specific options, please contact Pall.

Table 1 : Nominal Length

Code	Description
1	254 mm (10”)
2	508 mm (20”)
3	762 mm (30”)
4	1016 mm (40”)

Table 2 : Adaptor

Code	Description
3	SOE – single open end with flat closed end and external 222 O-rings
7	SOE – single open end with fin end, 2 locking tabs and external 226 O-rings
28	SOE – single open end with fin end, 3 locking tabs and external 222 O-rings

Table 3 : O-ring Seal Material

Code	Description
H4	Silicone Elastomer
J	Ethylene Propylene Rubber

Table 4 : Cartridge Quantity

Code	Description
Blank	1
96*	96

* 96 available in 30” Code 7 only

Fuente polyethersulfone membrane filter cartridges are a unique combination of Ultipleat® filter construction and optimized built-in pre-filtration to give longer filter life and lower filtration costs.

Fuente filter cartridges are intended for use in food and beverage water filtration applications.

An initial flush is recommended prior to use.

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Quality Manager
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Fuente Filter Cartridges (AB Style "W" Code)

Components

Filter Media	Hyrophillic Supor® polyethersulfone membrane
Support / Drainage	Polypropylene
Cage	Polypropylene with titanium dioxide filler
Core, End Cap and Fin End	Polypropylene
Adaptor	Polypropylene with internal stainless steel reinforcing ring as appropriate to design
O-ring Seal	Ethylene Propylene Rubber (J) and Silicone Eastomer (H4)

Declaration

Fuente AB style "W" Code style filter cartridges comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

Europe

The "W" Code Fuente AB style filter cartridges meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

- Our suppliers' information indicates that the polymeric materials used to produce "W" Code Fuente AB style filter cartridges are made from monomers and additives consistent with Annex I of Commission Regulation (EU) Number 10/2011 and its amendments, relating to plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

  Migration testing of the Fuente materials of construction was performed, as part of an AB1EKV7P style Supor filter, and met migration criteria after flushing and in flow conditions in:
  Simulant A (10% ethanol)
  Simulant B (3% acetic acid)
  And distilled water

  Note:
  This product contains materials that are subject to Specific Migration Limit (SML) requirements.
  This product contains calcium stearate, which is approved as a direct food additive.

- Samples of the silicone elastomeric (H4) and EPR (J) seal material formulations, typically used with the above part numbers, have been tested as 226 size seals for overall migration. Testing was conducted in distilled water, 3% acetic acid and 20% ethanol, under reflux conditions for 4 hours - repeat use. In respect of the overall migration limit for food contact elastomers according to the French requirements (given in Arrete of November 9th 1994 and published in Journal Officiel de la Republique Francaise, December 2nd 1994, p17029-17036) is 10 mg/dm^2, data obtained with the rubber o-rings under the tested conditions was well within this limit.

- The volatile levels from samples of the silicone elastomer (H4) formulation, after heating at 200°C for 4 hours, was found to be within the BfR section XV specification for this material.

- Our supplier states that the EPR (J) seal formulation is suitable for food contact use under BfR XXI category 4.

Users should satisfy themselves that these materials are suitable for use in their specific food application.

USA

The materials of construction meet the FDA requirements for food contact use as detailed in Code of Federal Regulations, 21 CFR paragraphs 170-199:

- Ethylene Propylene Rubber and Silicone Elastomeric seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils)

- Examples of Supor membranes were analyzed as per ASTM test method for conformance to FDA specifications for food contact substance. The membrane met the specifications of polyethersulfone resins as detailed in Title 21 of the US Code of Federal Regulations 177.2440 paragraphs (a), (b) and (c) including acceptable heavy metal content. Additionally, no specified or known adjuvants were detected at a limit of 0.001 %.

While it is the responsibility of the user to determine the safety of equipment and materials for food contact applications, the data indicate that the composition of the Supor membranes are suitable for food contact since under the test conditions, no substances were detected that are not permitted as components of food contact substances.

Process Quality System

Site of Manufacture: Pall Manufacturing (UK) Ltd., Ilfracombe, UK on behalf of Pall International Sàrl.

The Quality Management System at Pall Manufacturing (UK) Ltd., Ilfracombe, is certified to ISO 9001:2008.
These products / product packaging carry a lot number / date code to facilitate traceability to suppliers' materials and Pall production records.

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