

DECLARATION OF COMPLIANCE

Fuente II Filter Cartridges

AB Style “W” Code

Cartridge Part Numbers

AB FFN W

Table 1
Table 2
Table 3

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
8	SOE - single open end - with fin closure end and external 222 O-Rings on open end.
28	SOE – single open end with fin end, 3 locking tabs and external 222 O-

Table 3 : O-ring Seal Material

Code	Description
H4	Silicone Elastomer
J	Ethylene Propylene Rubber

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

An initial flush is required prior to use.

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Mario Basters
 Quality Assurance & Regulatory Affairs Manager
 Pall Filtersystems GmbH

Fuente II Filter Cartridges (AB Style “W” Code)

Components

Filter Media	Hydrophillic Supor® polyethersulfone membrane
Support / Drainage	Polypropylene
Cage	Polypropylene
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 Elastomer (H4)

Declaration

Fuente II 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 II 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 II filter cartridges are made from monomers and additives consistent with Annex I of European 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 cartridges has been performed, after flushing and in flow conditions, in:-

10% ethanol

3% acetic acid

50% ethanol

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/dm², 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 (392 °F) 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 in that:

- Silicone Elastomeric seal material to 21 CFR section 177.2600 (Rubber articles intended for repeated use)
- Silicone Elastomeric seal material used conforms to 3-A Sanitary Standards 18-03 Class I for use with milk / butter oil products.

- Ethylene Propylene Rubber seal material to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils)
- Polypropylene to 21 CFR section 177-1520 (Olefin polymers).
- 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.

Note: this product may contain trace levels of titanium dioxide, a chemical known to the state of California to cause cancer. The listing for titanium dioxide is for "airborne, unbound particles or respirable size." The listing is not applicable to titanium dioxide within a product matrix such as polypropylene.

Process Quality System

Sites of Manufacture: Pall Filtersystems GmbH, Bad Kreuznach, Germany on behalf of Pall International Sàrl.

The Quality Management System at Pall Filtersystems GmbH, Bad Kreuznach are certified to ISO 9001:2015.

These products / product packaging carry a lot number / date code to facilitate traceability to suppliers' materials and Pall production records.

Pall Filtersystems GmbH confirms that the product manufacturing environment is in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

Supplied in Europe by

Pall International Sàrl
Av. de Tivoli 3
Fribourg
Switzerland
CH-1700




Pall Food and Beverage

New York - USA
+1 516 484 3600 telephone
+1 866 905 7255 toll free
foodandbeverage@pall.com

Visit us on the web at www.pall.com

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