PALL CORPORATION

DECLARATION OF COMPLIANCE
Fluorodyne® II Filter Cartridges
"W" Code

Cartridge Part Numbers

AB ☐ FSD ☐ 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
05*	127 mm (5")
1	254 mm (10")
2	508 mm (20")
3	762 mm (30")
4	1016 mm (40")

*Available only in Code 2.

Table 2 : Adaptor

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

Fluorodyne II filter cartridges are intended for use in the following applications: bottled water; water; and for dosing flavor, color, aqueous ingredients and other critical solutions into food and beverage products. The product is not intended for filtration of fatty foods.

The filter medium comprises a hydrophilic PVDF membrane.

An initial flush is recommended prior to use.

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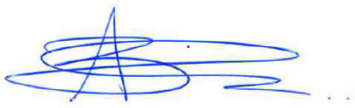
Reference FBDCFSDENe



Andrew Betts
Quality Manager
Pall Manufacturing (UK) Ltd., Ilfracombe

Fluorodyne II Filter Cartridges ("W" Code)

Components

Filter Media	Hydrophilic polyvinylidine fluoride (PVDF) membrane
Cage, Core, End Cap and Fin End	Polypropylene
Adaptor	Polypropylene with a stainless steel reinforcing ring as appropriate to the design
O-ring Seal	Ethylene Propylene Rubber (J) or Silicone Elastomer (H4)

Declaration

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

Europe

The "W" Code Fluorodyne 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 AB style Fluorodyne II products are made from monomers and additives consistent with Annex I of Commission Regulation (EU) Number 10/2011, relating to plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

  Migration testing of the filter components of the Fluorodyne II filters has been performed, and met migration criteria after flushing and in flow conditions in:
  10 % ethanol up to 100 °C (212 °F),
  And 65% ethanol up to 100 °C (212 °F)

  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 Officlel 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 (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 FDA requirements for food contact use as detailed in Code of federal Regulations, 21 CFR paragraphs 170-199 in that:

- Our suppliers state that base polymer materials used by Pall to manufacture the "FSDW" filter membrane and polypropylene components of the above Pall product are listed in 21 CFR 170-199:

- PVDF to 21 CFR section 177.2510 (Polyvinylidene fluoride resins) – excluding hydrophilicity
- Polypropylene to 21 CFR section 177.1520 (Olefin polymers)
- Hydrophilicity -- Membrane was analyzed as per ASTM D2857-95 test methods for conformance to FDA specifications for a food contact substance. The membrane met the specifications for polyvinylidene fluoride resins as described in Title 21 of the U.S. Code of Federal Regulations 177.2510 paragraphs (a), (b), and (c) including acceptable heavy metals content. Additionally, no specified or known adjuvants were detected at a limit of 0.001%.
- 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)

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 9001:2015.

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

Pall Manufacturing (UK) Ltd. confirms that the product is manufactured in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006

Supplied in Europe by

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