

# DECLARATION OF COMPLIANCE

## Fluorodyne® II Filter Cartridges

### “W” Code

### Cartridge Part Numbers



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

## Fluorodyne II Filter Cartridges (“W” Code)

### Components

Filter Media	Hydrophilic polyvinylidene 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).

OML and SML 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.

**French requirements for food contact elastomers (Arrêté of 9th November 1994 amended by order of 5th August 2020)** Typical samples of the ‘H4’ (Silicone) and ‘J’ (EPDM) seal material formulations have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 20 % ethanol, 50 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the ‘H4’ O-rings, under the test conditions, were well within the limit for all migration fluids tested. The data obtained with the ‘J’ O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid, 20 % ethanol and 50 % ethanol. The ‘J’ O-rings are not suitable for use in fatty foods.

**German requirements for food contact elastomers (BfR XV Silicones)** Typical samples of the ‘H4’ (Silicone) seal material formulation have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 10 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the ‘H4’ O-rings, under the test conditions, were well within the limit for all migration fluids tested.

**German requirements for food contact elastomers (BfR XXI Natural and Synthetic Rubber Category 1)** Typical samples of the ‘J’ (EPDM) seal material formulation have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 10 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the ‘J’ O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid and 10 % ethanol. The ‘J’ O-rings are not suitable for use in high alcohol or fatty foods. Additionally, our supplier states that this O-ring 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 supplied by Pall Sàrl. Made in UK.

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

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



+1-866-905-7255 **Food and Beverage toll free**  
foodandbeverage@pall.com

**Corporate Headquarters**  
Port Washington, NY, USA  
+1-800-717-7255 toll free (USA)  
+1-516-484-5400 phone

**European Headquarters**  
Fribourg, Switzerland  
+41 (0)26 350 53 00 phone


**Asia-Pacific Headquarters**  
Singapore  
+65 6389 6500 phone

**Visit us on the Web at [www.pall.com/foodandbev](http://www.pall.com/foodandbev)**

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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

*IF APPLICABLE* Please contact Pall Corporation to verify that the product conforms to your national legislation and/or regional regulatory requirements for water and food contact use..

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