

# DECLARATION OF COMPLIANCE

## Fluorodyne® II Filter Cartridges, JSD

### “W” Code

### Cartridge Part Numbers

AB  JSD  WH4  
Table 1                      Table 2

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
7	SOE – single 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

\*available in AB3 only

Fluorodyne II filter cartridges (JSD) are intended for use in water and bottled water applications and excludes filtration of fatty foods. The filter medium comprises a hydrophilic PVDF membrane.

An initial flush is recommended prior to use.

Issued            6 December 2017  
 Revised        11 February 2021  
 Expires         28 February 2023  
 Reference      FBDCJSDENb  
 Page            1 of 3



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

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

### Components

Filter Media	Hydrophilic polyvinylidene fluoride (PVDF) membranes
Cage, Core, End Cap and Fin End	Polypropylene
Adaptor	Polypropylene with a stainless steel reinforcing ring as appropriate to the design
O-ring Seal	Silicone Elastomer (H4)

### Declaration

Fluorodyne II “W” Code filter cartridges (JSD) 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).

#### 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) 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<sup>2</sup>, 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.

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 "JSDW" 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%.
- 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.

Pall Manufacturing (UK) Ltd., Ilfracombe, confirm that the product manufacturing environment, for the above products at our site, 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](http://www.pall.com)

Pall Corporation has offices throughout the world. For Pall representatives in your area, please go to [www.pall.com/contact](http://www.pall.com/contact).

Because of developments related to products, systems and/or services described herein, the data and procedures are subject to change without notice. Please consult your Pall representative or visit [www.pall.com](http://www.pall.com) to verify that this information remains valid.

© Copyright 2021, Pall Corporation. Pall,  and Fluorodyne are trademarks of Pall Corporation. ® indicates a trademark registered in the USA.  
*Filtration. Separation. Solution.™*