PALL CORPORATION

# DECLARATION OF COMPLIANCE
# Fluorodyne* II Filter Cartridges
## MCY Junior Style "W" Code

## Cartridge Part Number

MCY ☐ FSD WH4

Table 1

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

**Table 1 : Nominal Length**

| Code | Length | Description |
|---|---|---|
| 4440 | 105 mm (4.1") | Plug seal adaptor with locating fin and double external O-ring seals |
| 4463 | 136 mm (5.3") | Single 116 O-ring and internal plug seal |

Fluorodyne II Junior Style filter cartridges are intended for dosing flavor, color, aqueous ingredients and other critical solutions into food and beverage products. This filter is not suitable for the filtration of fatty foods.

The filter medium comprises a hydrophilic PVDF membrane.

An initial flush is recommended prior to use.


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Pall Sàrl and MEA QARA Manager

## Fluorodyne II Junior Style Filter Cartridges ("W" Code)

### Components

| | |
|---|---|
| Filter Media | Hydrophilic polyvinylidine fluoride (PVDF) membrane |
| Cage, Core, and End Cap | Polypropylene |
| Adaptor | Polypropylene |
| O-ring Seal | 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 Junior Style Fluorodyne II products are made from monomers and additives consistent with Annex I and II of Commission Regulation (EU) Number 10/2011, relating to plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

Migration testing (OML and SML) of the Fluorodyne II Junior Style filter has been performed, and meets migration criteria after flushing and in flow conditions at greater than 0.05 kg/hr per filter in:
Simulant A (10 % ethanol) for 2 hours up to 40 °C (104 °F),
Simulant B (3 % acetic acid) for 2 hours up to 40 °C (104 °F),
and Simulant D2 (95 % ethanol) for 2 hours up to 40 °C (104 °F),
under repeated use conditions

Additionally, migration testing of the filter components of Fluorodyne II filters have been performed and met migration criteria after flushing and in flow conditions in:
Simulant A (10 % ethanol) for 4 hours up to 100 °C (212 °F)
and 65 % ethanol for 4 hours 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) seal material formulation 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.

**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.

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:

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%.
- 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: Manufactured in the UK and supplied by Pall Sàrl. Made in the UK.

The Quality Management System at the manufacturing site 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 Sàrl confirms that this 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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Pall Corporation has offices and plants throughout the world. To locate the Pall office or distributor nearest you, visit www.pall.com/contact.

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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