

# DECLARATION OF COMPLIANCE

## Poly-Fine® II Filter Cartridges

### “W” Code

### Cartridge Part Number



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

**Table 1 : Removal Rating**

Code	Description
025	0.25 µm
045	0.45 µm
08	0.8 µm
2	2 µm
3	3 µm
5	5 µm
10	10 µm
30	30 µm

**Table 2 : Nominal Length**

Code	Description
<b>DOE Style Only</b>	
975	248 mm (9.75")
10	254 mm (10")
195	495 mm (19.5")
20	508 mm (20")
2925	743 mm (29.25")
295	749 mm (29.5")
30	762 mm (30")
39	991 mm (39")
40	1016 mm (40")
<b>SOE Style Only<sup>1</sup></b>	
10	254 mm (10")
20	508 mm (20")
30	762 mm (30")
40	1016 mm (40")

<sup>1</sup>Please contact Pall for specific SI option length dimensions

**Table 4 : Adaptor**

Code	Description
Blank	DOE - double open end with end caps and gaskets
M3	SOE - single open end with flat closed end and external 222 O-rings
M4	SOE - single open end with fin end, 3 locking tabs, and external 222 O-rings
M7	SOE - single open end with fin end, 2 locking tabs, and external 226 O-rings
M8	SOE - single open end with fin end and external 222 O-rings
SI	SOE - single open end (end cap with gasket) and stainless steel spring/polypropylene cap on closed end

**Table 3 : O-ring/Gasket Seal Material**

Code	Description
S	Silicone Elastomer <sup>2</sup>
E	Ethylene Propylene Rubber

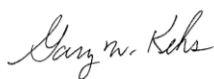
<sup>2</sup>For M3, M4, M7 and M8 options only

Poly-Fine II pleated filter cartridges are manufactured of all polypropylene materials<sup>3</sup>. They are designed for particle removal in liquids of all food types, which do not soften, swell or adversely affect their materials of construction. In addition, selected grades are used for particle removal in air/gas pre-filtration.

<sup>3</sup> SI option includes stainless steel spring

An initial flush is recommended prior to use.

Issued                      28 February 2017  
 Expires                    28 February 2019  
 Reference                FBDCPFINEIIEA  
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 Pall Timonium, USA

## Poly-Fine II Filter Cartridges (“W” Code)

### Components

Filter Media	Polypropylene
Core, Cage, Support, Drainage	Polypropylene
End Cap and Fin End	Polypropylene
Adaptor	Polypropylene
O-ring Seal	Silicone Elastomer (S) or Ethylene Propylene Rubber (E)
Gasket Seal	Ethylene Propylene Rubber (E)
Spring	Stainless Steel (SI Option only)

### Declaration

Poly-Fine II series “W” Code filter cartridges comprise materials that meet regulatory and legislative requirements and guidelines for food contact in that:

#### Europe

The “W” Code Poly-Fine II series filter cartridges meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

- Our suppliers state that the polymeric materials of construction are made from monomers and additives consistent with Annex I of Commission 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 the polypropylene materials of construction was performed in the following simulants for use after flushing and in flow conditions:

Simulant B (3% acetic acid) at 100 °C (212 °F) for 2 hours

Simulant C (20% ethanol) at 100 °C (212 °F) for 2 hours

Simulant D1 (50% ethanol) at 100 °C (212 °F) for 2 hours

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 material formulation used to manufacture the O-ring seals employed on the “W” code Poly-Fine II series filters 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 is 10 mg/dm<sup>2</sup> 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). 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 O-ring seal formulation, after heating at 200 °C for 4 hours, was found to be within the BfR section XV specification for this material.
- Our supplier states that the EPR 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:

- Polypropylene to 21 CFR section 177.1520 (Olefin polymers)
- Silicone Elastomer and Ethylene Propylene Rubber 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 Timonium, USA

The Quality Management System at Pall Timonium is certified to ISO 9001:2008.

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

## Supplied in Europe by

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February 2017