

# DECLARATION OF COMPLIANCE

## Poly-Fine® II Filter Cartridges

### “W” Code

### Cartridge Part Number

PFT   U   W 480

Table 1   Table 2   Table 3   Table 4

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

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

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

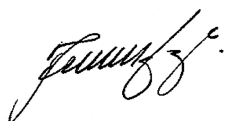
Code	Description
S	Silicone Elastomer <sup>2</sup>
E**	Ethylene Propylene Rubber

<sup>2</sup>For M3, M4, M7 and M8 options only   **\*\***Not suitable for use in fatty foods

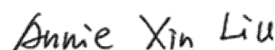
Poly-Fine II pleated filter cartridges are manufactured of all polypropylene materials<sup>3</sup>. They are intended for particle removal in general food and beverage application use. In addition, selected grades are used for particle removal in air/gas pre-filtration.

An initial flush is recommended prior to use.

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## 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 and II 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).

OML and SML migration testing has been performed, and met migration criteria after flushing and in flow conditions in:

- Simulant B (3% acetic acid) 2 hours at reflux,
- Simulant D1 (50% ethanol) 2 hours at reflux,
- Simulant D2 (Sunflower oil) 48 hours at 40 °C,
- And water up to 70 °C (158 °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 ‘S’ (Silicone) and ‘E’ (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 ‘S’ O-rings, under the test conditions, were well within the limit for all migration fluids tested. The data obtained with the ‘E’ O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid, 20 % ethanol and 50 % ethanol. The ‘E’ O-rings are not suitable for use in fatty foods.

**German requirements for food contact elastomers (BfR XV Silicones)** Typical samples of the ‘S’ (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 ‘S’ 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 ‘E’ (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 ‘E’ O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid and 10 % ethanol. The ‘E’ 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.

### **Mercosur**

The materials of construction meet the requirements for food contact as detailed in Reglamento Técnico Mercosur sobre materiales lista positiva de

- monómeros, otras sustancias de partida y polímeros autorizado para la elaboración de envases y equipamientos plásticos in contacto con alimentos, Mercosur/GMC/Res. No. 02/12 y
- aditivos para materiales plásticos destinados a la elaboración de envases y equipamientos in contacto con alimentos, Mercosur/GMC/Res. No 39/19.

### **People's Republic of China**

The Poly-fine II “W” code filter cartridges meet the requirements for food contact use as detailed in the following standards:

- GB 4806.1-2016 General Safety Requirements of Food Contact Material and Articles
- GB 4806.7-2016 Food Contact Plastic Materials and Articles
- GB 4806.11-2016 Food Contact Rubber Material and Articles
- GB 31603-2015 General Health Code for Production of Food Contact Material and Articles

Overall migration testing was conducted in 4% acetic acid under 2 hours at 100 °C, 10% ethanol under 2 hours at reflux condition, 95% ethanol under 3.5h at 60 °C, and isooctane under 1.5 hours at 60 °C -repeat use. The data obtained were well within the limit.

Typical samples of “E” and “S” O-rings were tested as GB4806.11 for overall migration, the data obtained were well within the limit for 4% acetic acid under 2 hours at 100 °C, 10% ethanol, and 95% ethanol under 2 hours at reflux temperature-repeat use.

### **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)
- Ethylene Propylene Rubber seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use with aqueous foods, excluding fatty foods (e.g. milk and edible oils)) based on confirmatory testing as detailed in section (e).
- Silicone Elastomer seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use, with aqueous and fatty foods (e.g. milk and edible oils)) based on confirmatory testing as detailed in sections (e, f).

### **Process Quality System**

Sites of Manufacture: Pall Timonium, USA Made in USA. Or Pall China, Beijing, People’s Republic of China. Made in China.

The Quality Management System at Pall Timonium and Pall Beijing 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 Timonium confirms that this product is manufactured in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006. Pall Beijing confirms that this product is manufactured in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

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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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