

# **DECLARATION OF COMPLIANCE**Profile® UP Filter Cartridges

AB Style "W" Code

# **Cartridge Part Number**



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

Table 1: Nominal Length

Code	Description
1	25.4 mm (10")
2	508 mm (20")
3	762 mm (30")
4	1016 mm (40")

Table 2: Removal Rating

Description
2 µm
4.5 µm
10 µm
20 µm
40 µm

Table 3: Adaptor

Code	Description
3	SOE – single open end
	with flat closed end and
	external 222 O-rings
7	SOE – single open 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

**Table 4: O-ring Seal Material** 

Code	Description
H4	Silicone Elastomer
J	Ethylene Propylene Rubber

Profile UP is a 2.5" diameter pleated filter cartridge intended for the filtration of aqueous food and beverage products (e.g. water and bottled water) and beverages with low alcohol concentrations such as beer.

An initial flush is recommended prior to use.

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Page 1 of 3

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Quality Director - Americas

#### Components

Filter Media Pall proprietary melt blown media
Support / Drainage Extruded polypropylene netting
Helical Wrap Polypropylene non-woven fabric
Cage, Core, End Cap

and Fin End Polypropylene

Adaptor Polypropylene with a stainless steel reinforcing ring as appropriate to design

O-ring Seal Ethylene Propylene Rubber (J) or Silicone Elastomer (H4)

#### **Declaration**

Profile UP AB style "W" Code filter cartridges comprise materials that meet regulatory and legislative requirements and guidelines for food contact in that:

#### Europe

The "W" Code AB style Profile UP filter cartridges meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

The materials used to produce "W" Code AB style Profile UP products meet the requirements of Annex I of European Commission Regulation (EU) Number 10/2011, and its amendments, on plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

OML and SML migration testing of the filters and components of the Profile UP filters has been performed, and met migration criteria after flushing and in flow conditions, in:

Simulants A (10% ethanol) at 50 °C (122 °F)

Simulant B (3% acetic acid) at 50 °C (122 °F)

Distilled water at 50 °C (122 °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.

#### Mercosur

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

- monómeros, otras substancias de partida y polímeros autorizado para la elaboración de envases y equipamientos plásticos in contacto con alimentos, Mercosur/GMC/Res. No. 19/21 y
- aditivos para materiales plásticos destinados a la elaboración de envases y equipamientos in contacto con alimentos, Mercosur/GMC/Res. No. 56/92.

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

The "W" Code AB style Profile UP filter cartridges meet the requirements for food contact as detailed in Chinese standard Numbers GB 4806.7-2023 and GB 4806.11-2023.

#### **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:

- Polypropylene to 21 CFR section 177.1520 (Olefin polymers) and section 178.2010 (antioxidants and/or stabilizers for polymers)
- Ethylene Propylene Rubber and Silicone Elastomeric seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use) and conform to 3-A sanitary standard 18-03 Class I for use with milk/butter oil products.

#### **Process Quality System**

Site of Manufacture: Pall Cortland, USA. Made in USA.

The Quality Management System at Pall Cortland 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 Cortland 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

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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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