

# DECLARATION OF COMPLIANCE

## PREcart PP II Filter Cartridges

“W” Code

### Cartridge Part Number

499A  W    P

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
110	1 µm
120	2 µm
130	3 µm
150	5 µm
210	10 µm
220	20 µm
250	50 µm

**Table 2 : 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 and external 226 O-rings
8	SOE – single open end with fin end and external 222 O-rings
22	DOE – double open end with end caps and gaskets *
221	DOE – double open end with end caps and gaskets *
41	SOE – single open end with fin end, 3 locking tabs and external 222 O-rings

**Table 3 : Nominal Length\***

Code	Description
1	254 mm (10")
2	508 mm (20")
3	762 mm (30")
4	1016 mm (40")

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

Code	Description
S	Silicone Elastomer
E	Ethylene Propylene Rubber

\*Please confirm DOE cartridge length for proper fit.

PREcart PP II filter cartridges are designed as a pre-filter for particulate removal from liquids. These filters may be used for the filtration of non-alcoholic beverages, slightly alcoholic beverages (such as beer and wine) and distilled spirits, excluding fatty foods.

An initial flush is recommended prior to use.

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Syed Sirajuddin  
 Pall Sàrl and MEA QARA Manager

## PREcart PP II Filter Cartridges (“W” Code)

### Components

Filter Media	Polypropylene
Support / Drainage	Polypropylene
Cage, Core, End Cap and Fin End	Polypropylene
Adaptor	Polypropylene with a stainless steel reinforcing ring*
O-ring/ Gasket Seal	Silicone Elastomer (S) or Ethylene Propylene Rubber (E)

\* in 03, 07, 08 and 41 configurations only

### Declaration

PREcart PP II filter cartridges are comprised of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

#### Europe

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

Our suppliers state that the components of construction are made from monomers and additives listed in Annex I and II of EU Regulation (EC) number 10/2011 and its amendments relating to plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

SML and OML migration testing has been performed on the filter materials of the PREcart PP II filters and met migration criteria after flushing and in flow conditions, in:

Simulant B (3% acetic acid) at 40 °C (104 °F), 30 min

Simulant D1 (50% ethanol), at 40 °C (104 °F), 30 min.

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.

Our supplier states that the ingredients of the silicone elastomeric material employed are in compliance with Recommendation XV of the BfR and Arrêté du 25 novembre 1992. Testing has been undertaken on samples of the Ethylene Propylene Rubber seal material and met LFGB requirements.

**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. 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 PREcart PP II filter cartridges meet requirements for food contact materials as detailed in GB 4806.1-2016. These filters meet the requirements detailed in Chinese standard Numbers GB 46806.7-2023 and GB 4806.11-2016. OML and SML migration testing of cartridges (excluding seals) has been performed and met migration criteria after flushing and in flow meeting the requirements for use.

### **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)
- Ethylene Propylene Rubber and 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 Germany and supplied by Pall Sàrl. Made in Germany

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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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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