

DECLARATION OF COMPLIANCE Profile® Star Filter Cartridges “W” Code

Cartridge Part Numbers

AB W
Table 1 Table 2 Table 3 Table 4

AB TF W
Table 1 Table 3 Table 4

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

Code	Description
A010	1 µm
A015	1.5 µm
A030	3 µm
A050	5 µm
A100	10 µm
A200	20 µm
A400	40 µm

Table 3 : Adaptor

Code	Description
2*	SOE – single open end with flat closed end, 2 locking tabs and external 226 O-rings
3	SOE – single open end with flat closed end and external 222 O-rings
7	SOE – single 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
28	SOE – single open end with fin end, 3 locking tabs and external 222 O-rings

Table 4 : O-ring Seal Material

Code	Description
H4	Silicone Elastomer
J	Ethylene Propylene Rubber

*Not available in TF.

Profile Star pleated depth filter cartridges are manufactured using all polypropylene materials. They are designed for particle and gel removal in liquids and air/gas particle removal in food and beverage applications.

An initial flush is recommended prior to use in liquids.

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Profile Star Filter Cartridges (“W” Code)

Components

Filter Media pack	Polypropylene
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 Star “W” Code filter cartridges are comprised of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

Europe

The “W” Code Profile Star 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 used to produce “W” Code AB style Profile Star products 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 filters and components of the Profile Star filters has been performed, and met migration criteria after flushing and in flow conditions in:
Simulant A (10% ethanol)
Simulant B (3% acetic acid)
And also in distilled water

In addition migration testing of the AB hardware and media materials have been performed for 2 hours at 100 °C in Simulant C (20% ethanol).

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 (H4) and EPR (J) seal material formulations, typically used with the above part numbers, 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 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) is 10 mg/dm², 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 (H4) formulation, after heating at 200° for 4 hours, was found to be within the BfR section XV specification for this material.

Our supplier states that the EPR (J) 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 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: Pall Manufacturing (UK) Ltd., Ilfracombe, UK on behalf of Pall International Sàrl.

The Quality Management System at Pall Manufacturing (UK) Ltd., Ilfracombe, 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.

Pall Pall Manufacturing (UK) Ltd., Ilfracombe, confirm that the product manufacturing environment, for the above product at our site, is in-line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

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