

DECLARATION OF COMPLIANCE

Profile[®] II Filter Cartridges

RMF Style “W” Code

Cartridge Part Number

RM F W
Table 1 Table 2

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")
29	736.6 mm (29")
3	762 mm (30")
4	1016 mm (40")

Table 2 : Removal Rating

Code	Description
005	0.5 µm
010	1 µm
030	3 µm
050	5 µm
100	10 µm
200	20 µm
400	40 µm

RMF Profile II filter cartridges comprise of a polypropylene filter medium cylindrical sleeve formed by a proprietary Pall process with a polypropylene molded core with integral end cap / seal closures.

Profile II RMF style filter medium does not contain surfactants or binder resins.

RMF Profile II filter cartridges are suitable for use in aqueous-based food and beverage applications, excluding fatty food.

An initial flush is recommended prior to use.

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 Reference FBDCPROFRMFENo
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Profile II Filter Cartridges (RMF Style “W” Code)

Components

Filter Media	Polypropylene
Core	Polypropylene
Elastomeric End Cap / Seal	Thermoplastic Elastomer material

Declaration

Profile II RMF Style “W” Code filter cartridges comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

Europe

The “W” Code RMF Profile 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 polymeric components 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 (excluding elastomeric endcap material) has been performed, and met migration criteria after flushing and in flow conditions, in;

Simulant B (3% acetic acid) for 2 hours at reflux
Simulant D1 (65% ethanol) for 2 hours at reflux
Distilled water for 2 hours at 70 °C (158 °F)

Migration testing of the elastomeric endcap material has been performed, and met migration criteria after flushing and in flow conditions, in;

Simulant A (10% ethanol), up to 70 °C (158 °F), for 2 hours
Simulant B (3% acetic acid), up to 70 °C (158 °F), for 2 hours
Simulant C (20% ethanol), up to 70 °C (158 °F), for 2 hours

Note:

This product contains materials that are subject to Specific Migration Limit (SML) requirements.

This product contains calcium stearate and amorphous silicon dioxide, which is approved as a direct food additive.

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.

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)
- Thermoplastic Rubber - Supplier states that the material is acceptable for use in food contact applications under 21 CFR §177.1810(B)(3) and Food Contact Notification (FCN) 679

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 9001:2015.

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

Pall Manufacturing (UK) Ltd. confirms that the product is manufactured in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006

Users should satisfy themselves that these materials are suitable for use in their specific food application.

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