

DECLARATION OF COMPLIANCE

Emflon® PFRW Filter Cartridges

MCY Junior Style “W” Code

Cartridge Part Number

MCY PFR 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	Length	Description
1110	32 mm (1.3")	Plug seal adaptor with locating fin and double external O-ring seals
2230	76 mm (3.0")	Single 116 O-ring and internal plug seal
3330	82 mm (3.2")	Plug seal adaptor with locating fin and double O-ring seals
4440	105 mm (4.1")	Plug seal adaptor with locating fin and double external O-ring seals
4463	136 mm (5.3")	Single 116 O-ring and internal plug seal

Table 2 : Seal material

Code	Description
H4	Silicone elastomer
J	Ethylene propylene rubber

Emflon PFRW final air filters are designed for gas filtration in the food and beverage industry, fermenter inlet air and exhaust venting, sterile process air and sterile venting of tanks in food and beverage processing.

The key feature of this product is the inclusion of two layers of hydrophobic, 0.2 µm microbially-rated Emflon PTFE medium in a polypropylene hardware filter construction.

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 Quality Manager
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Emflon PFRW Filter Cartridges (Junior Style “W” Code)

Components

Filter Media	Two layers of hydrophobic Emflon PTFE media
Support / Drainage	Polypropylene
Side Seal	Polypropylene
Cage, Core, End Cap and Fin End	Polypropylene
Adaptor	Polypropylene (The 2230 and 4463 style adaptors have an integral stainless steel reinforcing ring)
O-ring Seal	Silicone Elastomer (H4) Ethylene Propylene Rubber (J)

Declaration

Emflon PFRW Junior style “W” Code filter cartridges comprise materials that meet regulatory and legislative requirements and guidelines for food contact in that:

Europe

The “W” Code Emflon PFRW Junior style 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 these filters are made from monomers and additives listed in 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).

These articles are intended for indirect food use in filtration of gases, therefore migration testing is not applicable.

Note: This product contains calcium stearate, 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. No32/07.

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:

- PTFE to 21 CFR section 177.1550 (Perfluorocarbon resins)
- Polypropylene to 21 CFR section 177.1520 (Olefin polymers)
- Silicone Elastomeric seal material and Ethylene Propylene Rubber seal material 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 ISO9001:2015.

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

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

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