

DECLARATION OF COMPLIANCE Emflon® PFRW Filter Cartridges SBF Junior Style “W” Code

Cartridge Part Number

SBF1PFRW
Table 1

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

Table 1 : Seal material

Code	Description
H4	Silicone elastomer
J	Ethylene propylene rubber

Emflon PFRW SBF Junior Style 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.

'Sterile air' is defined as that filtered using a 0.2 µm liquid rated filter (capable of removing 10⁷ of *Brevundimonas diminuta* per cm² of effective filtration area, in laboratory tests). Please note this product is not supplied pre-sterilized.

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

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

Components

Filter Media	Two layers of hydrophobic Emflon PTFE media
Support / Drainage	Polypropylene
Hardware	Polypropylene
O-ring Seal	Silicone Elastomer (H4) Ethylene Propylene Rubber (J)

Declaration

Emflon PFRW SBF 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 SBF 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.

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:

- 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 ISO 9001:2008.

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

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