

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.

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.

Issued	1 March 2011
Revised	4 February 2021
Expires	28 February 2023
Reference	FBDCSBFPFRWENh
Page	1 of 3



Andrew Betts
 Quality Manager
 Pall Manufacturing (UK) Ltd., Ilfracombe

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.

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 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 9001:2015.

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.

Supplied in Europe by

Pall International Sàrl
Av. de Tivoli 3
Fribourg
Switzerland
CH-1700




Pall Food and Beverage

New York - USA
+1 516 484 3600 telephone
+1 866 905 7255 toll free
foodandbeverage@pall.com

Visit us on the web at www.pall.com

Pall Corporation has offices throughout the world. For Pall representatives in your area, please go to www.pall.com/contact.

Because of developments related to products, systems and/or services described herein, the data and procedures are subject to change without notice. Please consult your Pall representative or visit www.pall.com to verify that this information remains valid.

© Copyright 2021, Pall Corporation. Pall,  and Emflon are trademarks of Pall Corporation. ® indicates a trademark registered in the USA.