

# DECLARATION OF COMPLIANCE

## Emflon® PFRW Filter Cartridges

### SBF Junior Style “W” Code

#### Cartridge Part Number

SBFIPFRW

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.

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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.

**French requirements for food contact elastomers (Arrêté of 9th November 1994 amended by order of 5th August 2020)** Typical samples of the ‘H4’ (Silicone) and ‘J’ (EPDM) seal material formulations have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 20 % ethanol, 50 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the ‘H4’ O-rings, under the test conditions, were well within the limit for all migration fluids tested. The data obtained with the ‘J’ O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid, 20 % ethanol and 50 % ethanol. The ‘J’ O-rings are not suitable for use in fatty foods.

**German requirements for food contact elastomers (BfR XV Silicones)** Typical samples of the ‘H4’ (Silicone) seal material formulation have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 10 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the ‘H4’ O-rings, under the test conditions, were well within the limit for all migration fluids tested.

**German requirements for food contact elastomers (BfR XXI Natural and Synthetic Rubber Category 1)** Typical samples of the ‘J’ (EPDM) seal material formulation have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 10 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the ‘J’ O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid and 10 % ethanol. The ‘J’ O-rings are not suitable for use in high alcohol or fatty foods. Additionally, our supplier states that this O-ring 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.

## 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:

- 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 supplied by Pall Sàrl. Made in UK.

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.

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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

*IF APPLICABLE* Please contact Pall Corporation to verify that the product conforms to your national legislation and/or regional regulatory requirements for water and food contact use..

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