

DECLARATION OF COMPLIANCE

Emflon® HTPFR Filter Cartridges

AB Style “W” Code

Cartridge Part Number



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

Table 1 : Nominal Length

Code	Description
05*	127 mm (5")
1	254 mm (10")
2	508 mm (20")
3	762 mm (30")

*Available in code 2 only

Table 2 : Adaptor

Code	Description
2*	SOE – single open end with flat end, 2 locking tabs and external 226 O-rings
7	SOE – single open end with fin end, 2 locking tabs and external 226 O-rings

*Available in 5" only

Table 3 : Seal Material

Code	Description
H4	Silicone elastomer
J	Ethylene propylene rubber

Emflon HTPFRW final air filters are designed for critical, high temperature sterile filtration of compressed air and gas and sterile hot fluid tank venting applications in the food and beverage industry. They can also be considered for use in oxygen-enriched air applications.

The key features of this product are the inclusion of two layers of hydrophobic, 0.2 µm microbially-rated Emflon PTFE medium, polyphenylene sulfide support and drainage layers, and oxidation-resistant polypropylene hardware for resistance to highly oxidizing conditions.

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Emflon HTPFR Filter Cartridges (AB Style “W” Code)

Components

Filter Media	Two layers of hydrophobic Emflon PTFE media
Support / Drainage	Polyphenylene sulfide
Side Seal	Polypropylene
Cage	Polypropylene with silica/TiO ₂ filler
Core, End Cap and Fin End	Polypropylene
Adaptor	Polypropylene (with integral stainless steel reinforcing ring as appropriate to design*)
O-ring Seal	Silicone Elastomer (H4) Ethylene Propylene Rubber (J)

*For applications requiring autoclaving or steam sterilization, Pall recommends the use of Code 2 or Code 7 adaptors to ensure sealing after cooling. Cartridges should be cooled to system operating temperature prior to use.

Declaration

Emflon HTPFR AB 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 HTPFRW AB 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 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).

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) and 21 CFR 178.3297 (colorants for polymers)
- Polyphenylene sulfide has FCN number 40 for use as a polymeric component of repeated food use articles
- Fiber finish to 21 CFR section 177.2800 (Textiles and Textile fibers)
- 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).

Note: this product may contain trace levels of titanium dioxide, a chemical known to the state of California to cause cancer. The listing for titanium dioxide is for "airborne, unbound particles or respirable size." The listing is not applicable to titanium dioxide within a product matrix such as polypropylene.

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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Pall Corporation has offices and plants throughout the world. To locate the Pall office or distributor nearest you, visit www.pall.com/contact.

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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