

PRODUCT SAFETY DATA INFORMATION

Date: 30 November 2017

Data Sheet Number: PSDS2011/2/a Revision: 2

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Pall® disposable filter cartridges, employing PTFE filter membranes within a fluid contact polypropylene construction (supporting materials, and hardware) fitted with either a silicone elastomer, or ethylene propylene rubber O-ring seal option, plus a non-wetted stainless-steel adaptor reinforcing ring.

Example Product name(s): **Emflon® PFR and PFA membrane filter products.**

Example Part Number(s): See Appendix 1.

Those filters detailed above are intended for gaseous and vent filtration and separation in conditions which do not soften, swell or adversely affect the filter, or its materials of construction. For use in line with Pall's instructions for use and within published recommended use conditions.

For further information on Emflon filters or other Pall products, please visit Pall at <https://www.pall.com/en/about-pall.html>

SECTION 2 - Hazards Identification

Product definition: Article.

These products are not classified as hazardous according to REACH Regulation 1907/2006, or European CLP/GHS Regulation 1272/2008.

GHS Signal word: No signal word.

Hazard statements: No known significant effects or critical hazards.

Special packaging requirements: Not applicable.

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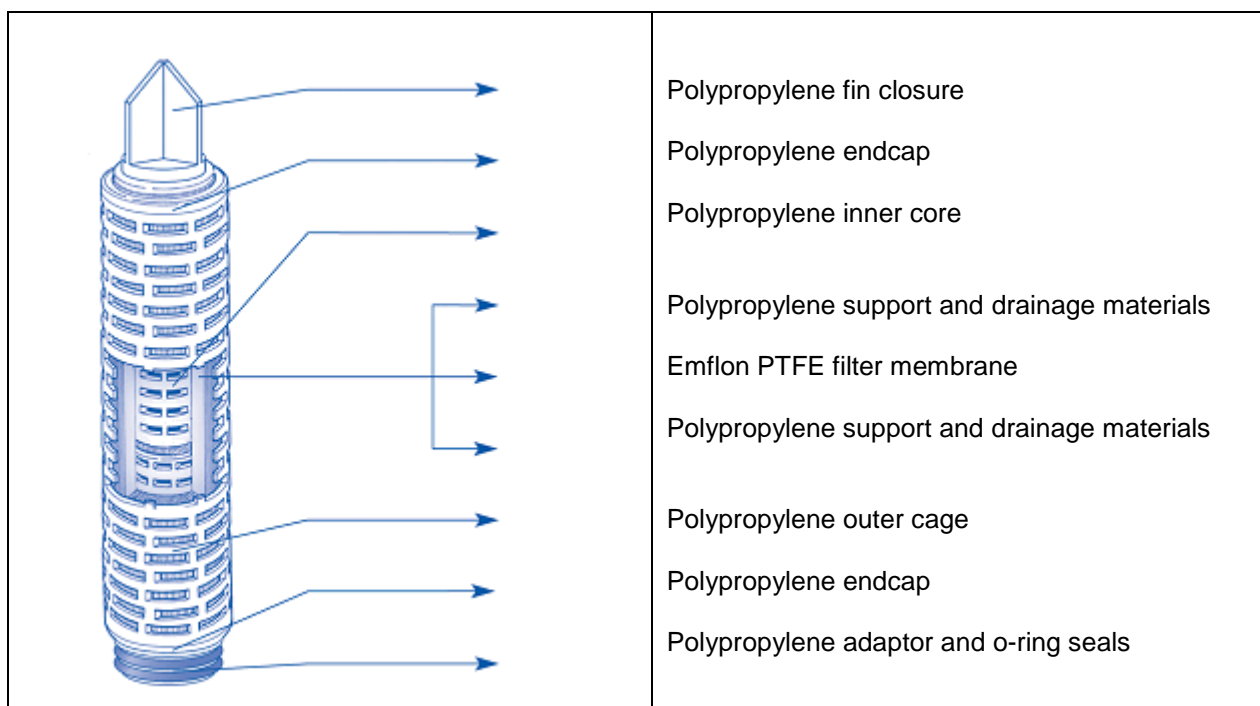
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SECTION 3 – Materials of Composition

3.1 The filters detailed in Section 1.1 are comprised of the following materials:

Material Name	Cas Number	Weight % (based on AB1 style element)
Polypropylene	9003-07-0	85-95 %
Polytetrafluoroethylene (PTFE)	9002-84-0	<10 %
Silicone elastomer seals or Ethylene Propylene Rubber (EPR)O-Ring seals	-	<2%
Stainless-steel reinforcing ring*		<2%



*Stainless-steel reinforcing ring as standard, - see Appendix 1 for further details. These components are not intended to be in the fluid pathway.

These products are not known to contain BADGE, NOGE, or BFDGE.

Trace additives will be present in the plastic components - for example polypropylene antioxidants are present for stabilisation purposes.

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the article.

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There are no current SVHC substances (including Bisphenol-A) known to be present in the finished articles above 0.1%.

There are no current ROHS2 Directive (2011/65/EU) and ROHS3 amendment (2015/863) substances of concern (including Lead, Cadmium, Mercury, Hexavalent Chromium, Polybrominated biphenyl (PBB), Polybrominated diphenyl ether (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Benzyl Butyl Phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) present in the polypropylene material employed in excess of the limits laid down, based on information from our suppliers and knowledge of substances used within Pall the manufacturing facility.

Emflon PFR and PFA products in 'P' and 'W' option do not contain materials of direct animal origin (i.e. animal parts, tissues, or body fluids). However polypropylenes are known to contain trace levels of additives (e.g. calcium stearate) which are derived from tallow. Please be advised that 'P' and 'W' grade products employ polypropylene materials in line with the CPMP's *Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathies via human and veterinary medicinal products* (EMA410/01 rev 3) which gives specific consideration to tallow derivatives and states they are unlikely to be infectious due to the rigorous processing steps used during their manufacture (an example of which is transesterification, or hydrolysis, at not less than 200°C under pressure for not less than 20 minutes).

SECTION 4 - First Aid Measures

4.1 First aid measures

Always consult the SDS details for the product being filtered, for specific in process advice and how to address any contaminants present on the filter as the result of use.

Eye Contact:	Eye injury could result from physical impact. Get medical attention immediately.
Inhalation:	Inhalation is not considered a likely route of exposure for the filter product as supplied by Pall.
Skin Contact:	Wash with soap and water. If irritation persists, get medical attention.
Ingestion:	This material is not intended for ingestion and is not expected to present an ingestion hazard in the form and quantities present in a work place setting. However if ingestion occurs, seek medical attention.
Protection of first-aiders:	No action shall be taken involving any personal risk or without suitable training.

4.2 Key symptoms and effects

No known significant effects or critical hazards related to the materials of construction of the filter as supplied.

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SECTION 5 - Fire Fighting Measures

5.1 Extinguishing media

Select an extinguish medium suitable for surrounding / working environment and consult the SDS of the product being filtered for specific advice.

For filter alone use dry chemical, CO₂, water spray (fog) or foam.

5.2 Specific Hazards

Warning: Combustion products of PTFE (fluoropolymers) can be released which are hazardous to humans and the environment.

Hazardous thermal decomposition products: CO, CO₂, Acrid Smoke, SO_x, benzenesulfonic acid, 2(or4) methyl- phenol,

Warning: thermal decomposition of PTFE can also produce fume particles, toxic gases, hydrofluoric acid and carbonyl fluoride.

Polymer fume fever – chills, nausea, shortness of breath, chest tightness, muscle or joint ache – seek immediate medical attention.

Consult the SDS details of product being filtered for specific advice.

5.3 Advice to Fire Fighters:

Special precaution required. Fire-fighters should wear appropriate protective equipment appropriate to fluoropolymer decomposition risks, including self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Protective gloves must be worn when handling debris after a fire, due to PTFE thermal decomposition risks.

SECTION 6 - Accidental Release Measures

Warning: Do NOT incinerate without additional consideration of risk emissions and residues resulting from combustion of PTFE – please see Section 13.

6.1 Personal precautions, protective equipment and emergency procedures

No special measures are required in respect of handling the filters in the unused condition as supplied.

6.2 Environmental precautions

For unused filter modules, place in designated waste container appropriate to the materials of construction listed in Section 3 and dispose of in accordance with local regulations via a licenced waste disposal contractor.

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For used filter modules, additionally consult the SDS details of the product being filtered for specific advice on spillage, using clear-up, containment and appropriate PPE measures related to the product being filtered and the materials of construction detailed in Section 3. Dispose of all waste in accordance with local regulations via a licenced waste disposal contractor.

6.3 Spillage containment and cleaning up

Collect the filter / material and place in a designated, labelled waste container.

Care should be taken to consider the nature of any contamination on the filter as the result of use and suitable PPE employed.

Dispose of waste via a licensed waste disposal contractor.

SECTION 7 – Handling and Storage

7.1 Handling:

Put on appropriate personal protective equipment for the working environment (See Section 8). Consult details of product being filtered for specific advice. Avoid activities that can damage the filter.

Follow good industrial hygiene practice. Eating, drinking and smoking are prohibited in areas where this product is handled, stored or processed. Workers must follow standard work-place hygiene before eating, drinking or smoking after using this product.

Wear gloves to prevent contamination of the filter cartridge and maintain cleanliness of the unused filter.

7.2 Storage:

In the received condition, special protective equipment is not needed during handling and normal use of these filters and o-ring seals. However, gloves are recommended to prevent contamination of the filter cartridge and maintain cleanliness. Handling of used filters must take into account the nature of the process fluids used and potential contaminant. The article is supplied dry, without the presence of any preserving fluid.

Store in a cool, clean environment.

Handle with care to avoid damage or abrading.

Store at temperatures between 0°C and 30°C, in dry conditions. For conditions outside of these limits consult Pall for specific recommendations.

Do not expose to direct sunlight or other radiation or direct weather conditions.

Store in original shipping bag or boxing.

Ensure careful handling to avoid physical damage. Ensure shipping bag and seals are intact prior to use. Plastics can be damaged if roughly handled – particularly at sub-zero temperatures. Thermal shock by quickly raising the temperatures from sub-zero should be avoided.

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Pall recommends a visual inspection prior to use. Do not use if the product or packaging is damaged (please contact Pall for further advice).

Please also consult the Pall instructions for use information on the product prior to use.

7.3 Shelf life

Pall recommends a customer shelf life of 5 years, from the date of manufacture, provided the product has been stored in accordance with the conditions laid out in section 7.2.

SECTION 8 - Exposure Controls/Personal Protection

8.1 Control parameters

Occupational Exposure limits: None required.

Recommended monitoring procedures: None required

8.2 Exposure controls

There are no special ventilation requirements for the article as supplied in the new and unused condition.

Hygiene Measures: No special measures required. Good hygiene practice in line with local working environmental requirements and industry guidelines.

Hand protection: Disposable gloves are recommended to ensure filter remains clean during installation.

Environmental Exposure Controls: Not normally required for the filter itself as supplied.

After the filter has been used additional exposure controls care should be taken in line with the nature of any contaminant on the filter as a result of its use.

SECTION 9 - Physical and Chemical Properties

Appearance: Filter Cartridge with elastomeric seals options. (see section 3.1)

Physical state: Solid

Colour: White filter, with optional silicone (tan / brick red) or EPR (black) colored elastomeric seals.

Melting Point: Typically >320°C for PTFE
Typically 160°C – 170°C for polypropylenes
Typically >200°C for elastomeric seals

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Auto-ignition temperature:	PTFE components: 520° - 560°C, thermal decomposition >300°C Polypropylene components: typically >301°C
Solubility:	Insoluble in water.
Sensitive to shock:	Mechanical / thermal shock can result in damage to the filter
Sensitive to Friction:	No.

SECTION 10 – Stability and Reactivity

Reactivity:	The filter is stable under the recommended conditions of use and storage.
Chemical Stability:	The filter is stable under recommended conditions of use and storage.
Hazardous Polymerisation:	Polymerisation will not occur.
Instructions for Use:	Consult Pall Instructions and Pall Technical Data sheets for Emflon filter products. Please also consider the SDS details of product being filtered for specific advice
Conditions to Avoid:	Avoid conditions that soften, swell or adversely affect the filter or its materials of construction. Do not allow fluids to freeze on the filter.
Incompatible Materials:	Polypropylene components and seals with oxidising materials.
Decomposition Products:	Warning: Combustion products of PTFE (fluoropolymers) can be hazardous to humans and the environment.

SECTION 11 - Toxicological Information

Materials of Construction: The following information is generic advice and provided for guidance only. For specific advice and recommendations also consult details of material being filtered.

11.1 Acute Toxicity

Consult details of product being filtered for specific advice and recommendations.

Based on typical information for the material type named, this information has not been determined specifically for Emflon PFR and PFA filters:

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Product/Ingredient Name	Result	Species	Dose	Exposure
Polypropylene	LD50 Oral	Rat	>8g/kg	-
PTFE	LD50	Rabbit	7.88 g/kg	dermal

Irritation / Corrosion / Sensitisation: No known concern
 Mutagenicity / Carcinogenicity / Reproductive Toxicity / Teratogenicity: No known concern for the materials of construction of the filter as supplied (new and unused)

Aspiration: No known concern for the materials of construction of the filter as supplied (new and unused)

Potential acute health effects: No known significant effects or critical hazards.

11.2 Chronic health effects:

Consult details of product being filtered for specific advice and recommendations.

General: No known significant effects or critical hazards.

Carcinogenicity: Classified 3 (Not classifiable for humans.) by IARC [Polypropylene].

Mutagenicity: No data available.

Teratogenicity: No data available.

Developmental Effects: No known significant effects or critical hazards.

Fertility Effects: No known significant effects or critical hazards.

Other information: No data available.

SECTION 12 - Ecological Information for clean, un-used polypropylene filters

The information in this section contains generic advice and guidance. For specific advice and recommendations consult details of material being filtered.

12.1 Toxicity No data available.

12.2 Persistence and Bio-degradability No data available.

12.3 Bio-accumulation potential No data available.

12.4 Soil/Water partition Coefficient (Koc) No data available.

12.5 Results of PBT and vPvB assessment

PBT No data available.

vPvB No data available.

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12.6 Other Adverse effects

No known significant effects or critical hazards.

12.7 Products of degradation

Emflon PTFE membrane and polypropylene filter components are not expected to degrade in contact with soil or water under ambient conditions. Consult details of product being filtered.

SECTION 13 - Disposal Information

The information in this section contains generic advice and guidance.

13.1 Product

Methods of disposal: Disposal/handling of the used and un-used filters should be in-line with national legislation and local regulatory requirements for the materials present. Unused filter cartridges may be used as land-fill if permitted by local legislation related to the materials of construction.

Warning: Do NOT incinerate unused filters with general waste, as combustion products of PTFE (fluoropolymers) can be released and be hazardous to humans and the environment.

Due consideration shall be made to the nature of the contaminants on the filters as a result of use and release of combustion products of PTFE.

Hazardous Waste: To the best of our knowledge, this product if un-used, is not regarded as hazardous waste as defined by the EU Directive 91/689/EEC and amendments. Due consideration must be made to the nature of the contaminants on the filters as a result of use, when considering whether the used filters are classified as hazardous waste.

13.2 Packaging

Bagging: Plastic (polyethylene)

Box: Cardboard

The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled where suitable arrangements and facilities exist. Incineration or land-fill should only be considered where re-cycling is not feasible.

SECTION 14 - Transport Information (Data for clean and un-used filter)

The clean and un-used filter, supplied in its original packaging, is not classified as dangerous goods under ADR, RID, IMDG or IATA regulations.

SECTION 15 - Regulatory Information**15.1 Safety, health and environmental regulations/legislation specific**

EU Regulation (EC) No. 1907/2006 (REACH):

See section 3.1

15.2 Other EU Regulations

Europe Inventory: Not determined

Black List Chemicals: Not Listed

Priority List Chemicals: Not Listed

Integrated pollution prevention and control List – Air: Not Listed

Integrated pollution prevention and control List – Water: Not Listed

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Note:

To the best of our knowledge, the information contained herein is accurate. However, neither the above Pall Corporation, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

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APPENDIX 1 –**Example part numbers including filters fitted with silicone elastomer or ethylene propylene rubber (EPR) seals.****Product:** **Emflon PFR ‘P’ option Filters (Biopharmaceutical applications)**

Part Number: AB *PFR_ _ _ % P ^

/here (*) indicates nominal filter length

(_ _ _) indicates media grade

(%) indicates cartridge code style – Code 3 and Code 8 only

(^) indicates the o-ring seal code: “H4”- silicone elastomer, “J” – EPR

Country of origin: Made in Puerto Rico, USA and the Ilfracombe, UK

Product: **Emflon PFR ‘W’ option Filters (Food and Beverage applications)**

Part Number: AB *PFR % W ^

/here (*) indicates nominal filter length

(%) indicates cartridge code style – stainless steel ring

(^) indicates the o-ring seal code: “H4”- silicone elastomer, “J” EPR

Country of origin: Made in the UK

Product: **Emflon PFA ‘P’ option Filters (Biopharmaceutical applications)**

Part Number: AB *PFA % P ^

where (*) indicates nominal filter length

(%) indicates cartridge code style – stainless steel ring

(^) indicates the o-ring seal code: “H4”- silicone elastomer, “J” – EPR

Country of origin: Made in Puerto Rico, USA and the UK

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Product: Emflon PFA 'W' option Filters (Food and Beverage applications)

Part Number: AB *PFA % W ^

Where (*) indicates nominal filter length

(%) indicates cartridge code style – stainless steel ring

(^) indicates the o-ring seal code: "H4"- silicone elastomer, "J" EPR

Country of origin: Made in the UK