Pall Corporation

PRODUCT SAFETY DATA INFORMATION

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SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Pall supported Polytetrafluoroethylene (PTFE) Emflon® hydrophobic membranes.

Example Product name(s): Polytetrafluoroethylene (PTFE) Emflon® hydrophobic membranes

Example Part Number(s): See Appendix 1.

The membrane filters detailed above are intended for venting, filtration, and separation applications with compatible fluids – 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.

PFOA is not intentionally added during the PTFE component manufacturing process for these membranes. However, these membranes may contain trace levels of PFOA and/or PFOA-related compounds.

For further information on 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.

Suitable gloves must be worn when handling these membranes out of their packaging, to address any concerns related to residual levels of PFOA related to the material as supplied.

GHS Signal word: No signal word.

Hazard statements: No known significant effects or critical

hazards. Special packaging requirements: None.

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SECTION 3 – Materials of Construction

3.1 The membranes detailed in Section 1 are comprised of the following materials:

Material Name	CAS Number	Percentage Composition
PTFE membrane	9002-84-0	16% to 17%
Non-woven polyester (LH0P) support material Polyethylene Terephthalate (PET)	25038-59-9	83% to 84%

Packaging Material	CAS Number
Polyethylene bagging	9002-88-4
PVC support core	9002-86-2

These products are not known to contain bisphenol-A diglycidyl ether (BADGE), Novolac glycidyl ethers (NOGE), or bisphenol-F diglycidyl ether (BFDGE).

Trace additives will be present in the plastic components- for example antioxidants are present for stabilization 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.

PFOA is not intentionally added during the PTFE component manufacturing process for these membranes. However, these products may contain trace PFOA and PFOA-related compounds at levels not known to exceed the current SVHC limits laid down in European REACH Regulation 1907/2006. Nor those limits for PFOA, its salts and PFOA-related compounds as detailed in European Regulation 2019/1021 related to Persistent Organic Pollutants, as amended by delegated regulation 2020/784 which came into effect on July 4th, 2020 and corrigendum published July 9th 2020.

The levels of PFOA, its salts and PFOA-related compounds are not known to exceed the limits applied in these requirements of:

- 25 ppb PFOA and its salts and
- 1000 ppb PFOA-related compounds

There are no current RoHS2 (Directive 2011/65/EU) and 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 Di-isobutyl phthalate (DIBP) known to be present in the materials employed in excess of the limits laid down, based on information provided by our suppliers and knowledge of substances used within the Pall manufacturing facility.

These membranes do not employ natural rubber latex, or latex derivatives, in their construction.

These products (see appendix 1) do not contain animal materials (i.e. animal parts, tissues, or body fluids). However, to assist our customers in performing a TSE/BSE risk assessment, we are pleased to provide the following information:

Pall filters for healthcare and laboratory applications may utilize components which are fabricated from plastic resins containing animal-derived additives at trace levels such as tallow-derived substances. Please be advised that tallow-derived additives are not considered specified BSE risk materials according to the current revision of the U.S. Code of Federal Regulations, Title 21 of part 189.5. Furthermore, the CPMP's *Note for guidance on minimising the risk of transmitting animal spongiform encephalopathies via human and veterinary medicinal products* (EMA410/01 rev 3) gives specific consideration to tallow derivatives and state 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).

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These products placed on the market in the State of California by Pall are not intended for 'consumer' sale, but, are for professional or industrial use. Therefore, the only anticipated exposure to these items would be through 'occupational exposure' which does not require mandatory labelling of all articles. In line with the 'Questions and Answers for business' (dated August 2017) on the labelling requirements – Q41 - this SDS convey this warning for occupational exposure.

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 membrane 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 membrane 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. 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, both acute and delayed

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

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 media use dry chemical, CO_2, water spray (fog) or foam.

5.2 Specific Hazards

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

Hazardous thermal decomposition products: CO, CO_2, 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.

Irritation to eyes - suitable PPE and breathing apparatus precautions should be taken related to this risk in the event of fire.

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5.3 Advice to Fire Fighters

Special precaution required. Fire-fighters should wear appropriate protective equipment, 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 – see Section 13.

6.1 Personal precautions, protective equipment and emergency procedures

Suitable gloves must be worn when handling these membranes out of their packaging, to address any concerns related to residual levels of PFOA related to the material as supplied.

No special measures are required in respect of the filter membrane in the unused condition as supplied.

6.2 Environmental precautions

For unused filter membrane, 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 licensed waste disposal contractor.

For used filter membrane, 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.

6.3 Spillage containment and cleaning up

Use suitable equipment to collect the filter membrane and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor.

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

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 membrane.

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 membrane and maintain cleanliness.

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7.2 Storage

In the received condition, suitable gloves must be worn when handling these membranes out of their packaging, to address any concerns related to residual levels of PFOA related to the material as supplied. Handling of used filter membranes must take into account the nature of the process fluids used and potential contaminants. The article is supplied dry, without the presence of any preserving fluid. Storage conditions:

1. Store at temperatures between 5°C and 30°C (14 - 86°F), in dry conditions
2. Do not expose to direct sunlight or other radiation or direct weather conditions.
3. Store in original shipping bag and boxing.
4. Exercise care during handling to avoid physical damage. Ensure shipping bag and any seals are intact prior to use. Membrane can be damaged if roughly handled, particularly at sub-zero temperatures. Thermal shock by quickly raising the temperature from sub-zero conditions should also be avoided.
5. Visual Inspection of packaging and product and, where appropriate, integrity testing is recommended prior to use. Do not use damaged articles.

For conditions outside the above or questions related to correct storage please contact Pall for further advice.

7.3 Shelf life

Pall recommends a customer shelf life of 3 years from the date of manufacture of the above articles, when the storage conditions in Section 7.2 are maintained.

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 membrane remains clean during installation.
Environmental Exposure Controls:	Not normally required for the filter membrane itself as supplied.

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

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SECTION 9 – Physical and Chemical Properties

Appearance:	Filter membrane sheet material
Physical state:	Solid
Color:	White
Melting Point:	Typically, 327°C for PTFE Typically, 260°C for polyethylene terephthalate
Flash Point:	Not applicable
Solubility:	Insoluble in water.
Auto-ignition temperature:	PTFE components: 520° - 560°C, thermal decomposition >300°C Polyester components > 390°C, thermal decomposition >300°C
Sensitive to shock:	Mechanical / thermal shock can result if damage to the filter

SECTION 10 – Stability and Reactivity

Reactivity:	The material is stable under the recommended conditions of use and storage.
Chemical Stability:	The material is stable under recommended conditions of use and storage.
Hazardous Polymerization:	Polymerization will not occur under recommended conditions of use and storage.
Other hazardous reactions:	Consult details of product being filtered for specific advice. Under normal conditions of storage and use, no hazardous reactions will occur.
Conditions to Avoid:	Avoid conditions that soften, swell or adversely affect the filter membrane or its materials of construction. Consult Pall if the filter membrane is to be used for continuous periods at 82°C or more. Do not allow fluids to freeze on the material.
Incompatible Materials:	Strong Acids, Strong Alkalis, Strong Oxidizing Agents.
Decomposition Products:	Under recommended conditions of use or storage, no hazardous decomposition products will be produced.

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SECTION 11 – Toxicological Information

The information in this section contains generic advice and guidance in respect of the unused filter membrane as supplied. Consult SDS details of the product being filtered for specific advice and recommendations.

11.1 Acute Toxicity

Irritation/Corrosion/Sensitization:	No known concern
Mutagenicity / Carcinogenicity / Reproductive Toxicity / Teratogenicity:	No known concern
Aspiration Hazard:	Not applicable for unused filter membrane.
Potential acute health effects:	No known significant effects or critical hazards for the unused filter as supplied.

11.2 Chronic health effects

No known significant effects or critical hazards for the unused filter as supplied.

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

SECTION 12 – Ecological Information

The information in this section contains generic advice and guidance related to hydrophobic, PTFE membrane.

PTFE membranes are not expected to degrade in contact with soil or water under ambient conditions.

Please also see information on PFOA and PFOA-related compounds in Section 3.

SECTION 13 – Disposal Information

The information in this section contains generic advice and guidance.

Product

Methods of disposal: Disposal/handling of the used and unused membranes should be in-line with national legislation and local regulatory requirements for the materials present. Unused membranes may be used incinerated via an approved process – however, these products may contain residual PFOA and PFOA-related compounds – which should be taken into account on thermal decomposition of the product and decision on incineration.

Due consideration shall be made to the nature of the contaminants on the filter membrane as a result of use.

Hazardous Waste**:** To the best of our knowledge, this product if unused 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 filter membrane as a result of use, when considering whether the used filters are classified as hazardous waste.

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Packaging

Bagging: Plastic (polyethylene)

Core: PVC

Box: Cardboard

The generation of waste should be avoided or minimized 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

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

SECTION 15 – Regulatory Information

Stockholm Convention on Persistent Organic Pollutants (POP) related to PFOA content. See section 1 above.

EU Regulation (EC) No. 1907/2006 (REACH): See section 3 above as amended by EC 2017/1000

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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Notice to Reader

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.

Final determination of suitability of any materials is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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APPENDIX 1

Example part numbers:

Part Number	Description
PTF002LH0P- ####	Emflon PTFE membrane, 0.02 µm
PTF020LH0P- ####	Emflon PTFE membrane, 0.2 µm
PTF045LH0P- ####	Emflon PTFE membrane, 0.45 µm
PTF100LH0P- ####	Emflon PTFE membrane, 1.0 µm

indicates unique filter membrane format and dimensions for a specific customer order

Country of Origin: Made in the U.S.A.

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