Pall Corporation

PRODUCT SAFETY DATA INFORMATION

Date: 17 December 2021

Data Sheet Number: PSDS2021/PPES Revision: 0

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Pall hydrophilic positive-charged polyethersulfone membrane.

Example Product name(s): Positive-Charged PES membranes

Example Part Number(s): See Appendix 1.

The filter membrane detailed above is intended for professional use 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 published recommended use conditions where available.

This product is not intended for food contact use.

For further information on Pall products, please visit Pall at https://www.pall.com/en/about-pall.html

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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: None.

SECTION 3 – Materials of Construction

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

Material Name	CAS Number	Percentage Composition
Polyethersulfone (PES) membrane	Pall proprietary	90 -98%
Additives	Pall proprietary	1 – 10%
Positive-charged surface treatment	Pall proprietary	0.1 – 5%

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 stabilisation purposes.

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the GHS / CLP risk classification of the article. There are no current European REACH SVHC substances known to be present in the finished articles above 0.1%.

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 from our suppliers and knowledge of substances used within Pall the manufacturing facility.

These Pall membranes do not employ natural rubber latex, or latex derivatives in its construction. In addition, Pall membranes do not knowingly contain materials of direct animal origin (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:

Certain plastics are known to contain trace levels of additive (e.g. calcium stearate) which are manufactured from tallow. Pall products may utilize components in the fluid pathway which are fabricated from plastic resins containing tallow-derived additives at trace levels, but Pall does not test for them.

Please be advised that bovine tallow-derived additives are not considered specified TSE/BSE risk materials according to the current revision of the U.S. Code of Federal Regulations, Title 21 of part 189.5, which defines specified risk material.

Furthermore, the Committee for Proprietary Medicinal Product (CPMP)'s Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathies via human and veterinary medicinal products (EMA410/01 rev 3) and Regulation (EU) 722/2012 EEC concerning medical devices manufactured using tissues of animal origin, give 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). The plastics raw materials Pall purchase have been processed with these steps. Pall continuously works to assure the safety of our products with respect to potential BSE/TSE transmission by working through our supply chain to obtain information regarding the possible use of animal-based material and to confirm specific sourcing and processing details where applicable.

The State of California requires 'clear and reasonable warnings' in respect of amounts of specific chemicals in the consumer products they purchase, in homes or workplaces or that are released into the environment. The aim of the warnings is to protect against chemicals known by the State of California to cause cancer, birth defects or reproductive harm. The list of substances of concern, form, and/or the concentration present above which notification for each substance is required (or 'safe harbor level') being that published by the State and known as the California Proposition-65 list.

Pall cannot at this time confirm that the residual level of the substances listed below would result in the indirect exposure of an individual to levels above their Cal Prop-65 threshold exposure limit, due to the wide range of migration scenarios that could be encountered in their use. However, inhalation or ingestion of these articles are considered unlikely scenarios – for sheet membrane materials. Also, as gloves are also recommended to be used when handling Pall's membranes to maintain cleanliness of the product, skin contact is also considered an unlikely exposure scenario.

Pall will continue to monitor updates to Proposition-65. Should you have any questions related to the information provided by Pall please do not hesitate to contact your local Pall Customer Services department.

These articles placed on the market in the State of California are not intended for 'consumer' sale and are for professional use, and as the result of use will be expected to be disposed of as 'hazardous waste' within an appropriate waste stream reflecting the contaminant present as the result of use. These articles are supplied in sealed bags and boxed. Hence,

any anticipated, direct contact with the materials of construction of those items is expected to be through 'occupational exposure', which does not require mandatory labelling of all articles.

These articles may contain trace residual levels of the following substances, but Pall does not test for them. These substances are listed below:

Substance	CAS#	Concentration range (% wt.)
N, N-Dimethylformamide (DMF)	68-12-2	0 - 0.099%
N-Methyl 2-Pyrrolidone (NMP)	872-50-4	0 - 0.099%

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 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 workplace 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 membrane alone use dry chemical, CO_2, water spray (fog) or foam.

5.2 Specific Hazards

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

For the filter membrane alone: No specific fire or explosion hazard. Hazardous thermal decomposition products:
CO, CO_2, Acrid Smoke.

5.3 Advice to Fire Fighters

No special precaution required related to the filter membrane alone. 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.

SECTION 6 – Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

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

For used filter membrane, always address any contaminants present on the membrane as the result of use.

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 licenced 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 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 for handling medical waste.

SECTION 7 – Handling and Storage

7.1 Handling

In the received condition, special protective equipment is not needed during handling and normal use of this filter membrane. However, gloves should be worn when handling the membrane material. This will additionally prevent contamination of the filter membrane and maintain cleanliness.

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.

Handling of used separation membranes must take into account the nature of potential contaminants and disposed of in line with local requirements related to medical waste.

Follow good industrial hygiene practice. Eating, drinking and smoking are prohibited in areas where this product is handled, stored or processed – exceptions are made on the guidance of local medical advice. Workers must follow standard work-place hygiene before eating, drinking or smoking after using this product.

7.2 Storage

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 5°C and 30°C (41°F – 86°F), 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.

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

7.3 Shelf life

Pall recommends a customer shelf life of 5 years, from the date of Pall 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 medical 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 and care should be taken in line with the nature of any contaminant on the filter membrane as a result of its use.

SECTION 9 – Physical and Chemical Properties

Appearance:	Filter membrane in disc, sheet or roll form
Physical state:	Solid
Colour:	White.
Melting Point	Typically, 230°C for PES polymers
Solubility:	Insoluble in water.
Auto-ignition temperature:	Not applicable
Sensitive to shock:	Mechanical / thermal shock can result in damage to the filter membrane

SECTION 10 – Stability and Reactivity

Reactivity:	The filter membrane is stable under the recommended conditions of use and storage.
Chemical Stability:	The filter membrane is stable under recommended conditions of use and storage.
Hazardous Polymerisation:	Polymerisation 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. Do not allow fluids to freeze on the filter.
Incompatible Materials:	Strong Acids, Strong Alkalis, Strong Oxidising Agents.
Decomposition Products:	Under recommended conditions of use or storage, no hazardous decomposition products will be produced.

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/Sensitisation:	No known concern to unused separation membranes as supplied.
Mutagenicity / Carcinogenicity / Reproductive Toxicity / Teratogenicity:	No known concern for the filter membrane as supplied (new and unused).
Aspiration Hazard:	Not applicable for un-used filter membrane.
Potential acute health effects:	No known significant effects or critical hazards for the unused filter membrane as supplied.

11.2 Chronic health effects

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

Carcinogenicity: No specific test data available.

SECTION 12 – Ecological Information

This filter membrane is not expected to degrade in contact with soil or water under ambient conditions.

SECTION 13 – Disposal Information

The information in this section contains generic advice and guidance.

Product

Methods of disposal: Disposal/handling of the used and un-used filter membranes should be in-line with national legislation and local regulatory requirements for the materials present. Unused membranes may be incinerated via an approved process in many countries – please check with local regulations and guidelines.

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 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 filter membrane as a result of use, when considering whether the used filter membranes are classified as hazardous waste. Therefore, used filter membranes may be classified as hazardous – clinical waste.

Packaging

Bagging:	Plastic (polyethylene)
Core:	PVC
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 landfill should only be considered where re-cycling is not feasible.

SECTION 14 – Transport Information

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

SECTION 15 – Regulatory Information

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

Blacklist 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.

APPENDIX 1

Part numbers:

Product: Positive-charged PES membranes

65738

65989

S80540

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