PRODUCT SAFETY DATA INFORMATION

Date: 25/11/2025

Data Sheet Number: PSDI MM20EV_membrane_Family Revision: AB

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Pall Medical MM20EV asymmetric polysulfone membranes.

Part Number(s): All part numbers in the scope of this document are listed in appendix 1. Unless specified in one of the following sections, all statements refer to all of the listed part numbers.

The membrane filters detailed above are for professional use only and designed for 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.

For further information on Pall Medical products, please visit www.Cytiva.com/pallmedical

SECTION 2 - Hazards Identification

Product definition: Article.

These products are not classified as hazardous according to current versions of UN Recommendations on the Transport of dangerous goods: Model regulations, GB Chemical classification, labelling and packaging (CLP) or European CLP/GHS Regulation 1272/2008 (current ATP)

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 products detailed in Section 1 are comprised of the following main materials:

Material Name	CAS Number	Percentage Composition
Polysulfone	Pall Medical proprietary information	90-99%
Additives	Pall Medical proprietary information	1-10%
PVC core	9002-86-2	N/A

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Regulations, Acts, Guidances, Notifications, Directives and miscellaneous substances of concern lists

Pall Medical continually monitors the Regulations, Acts, Guidances, Notifications and Directives listed below and in the event of a relevant update occurring, this PSDI will be updated and published to the website. PSDIs will not be updated simply to show reviews have occurred. The substances discussed below are not tested for by Pall Medical.

- Substances included in the REACH Candidate List of Substances of Very High Concern are not known to be present at a concentration > 0.1%
- Substances listed in the REACH restricted substances list (Annex XVII) with relevant restrictions or the REACH authorised substances list (Annex XIV) are not known to be present in the raw materials nor are they intentionally added in the manufacturing process.
- 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, their form, and/or the exposure level above which notification for each substance is required (or 'safe harbor level') being that published by the State and known as the Proposition-65 list. **These materials can potentially expose users to substances listed below which are known to the State of California to cause cancer and developmental toxicity.**

Substance	CAS#
N-Methyl 2-Pyrrolidone (NMP)	872-50-4
BPA	80-05-7

Pall Medical membranes and filters placed on the market in the State of California are not intended for 'consumer' sale but are for professional use. As the result of use they 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 and any direct contact with the materials of construction of those items is expected to be through 'occupational exposure', which does not require mandatory labelling of articles. Inhalation or ingestion of filters or sheet or roll membrane articles are considered unlikely scenarios. Also, as gloves are also recommended to be used when handling Pall Medical membranes to maintain cleanliness of the product, skin contact is also considered an unlikely exposure scenario.

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- Pall Medical does not specify, intentionally add or have any knowledge of the use of EU RoHS (also known as Directive 2002/95/EC and amendment 2015/863) or any other country RoHS listed materials in the raw materials it purchases, or the intended presence of these materials in any of its products.
- Substances of concern categories listed in the EU Waste Framework are not specified by Pall Medical in the raw materials nor are they intentionally added in the manufacturing processes, but Pall Medical does not test for them. Unused Pall Medical filters are not to the best of our knowledge classified as hazardous waste. Used filter cartridges should be disposed of as clinical waste due to the nature of the contaminants on the filters as a result of use. Therefore used filters may be classified as hazardous – clinical waste.
- Nanomaterials according to 2011/696/EU and nanomaterial forms of all other substances listed in this PSDI are not known to be present in the raw materials nor are they intentionally added in the manufacturing processes.
- Substances above 0.1 % (weight by weight) which are carcinogenic, mutagenic or toxic (CMR) for reproduction of category 1A or 1B in accordance with the current ATP to Part 3 of Annex VI to Regulation (EC) No.1272/2008 are not known to be present at a concentration > 0.1%.
- Substances having endocrine-disrupting (ED) properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in the article 59 of Regulation (EC) No. 1907/2006 or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 are not known to be present at a concentration > 0.1%,
- Substances listed in the Stockholm Convention are not known to be present in the raw materials nor are they intentionally added in the manufacturing process.
- The materials of construction and substances employed in making Pall Medical membranes and filters are not specified to have actively anti-microbial, anti-bacterial or other biocidal properties.
- Pall Medical does not specify, intentionally add or have any knowledge of the use of medicinal substances or combinations of substances that are absorbed by or locally dispersed in the human body from its suppliers and does not specify or have any knowledge of the use of such materials in the raw materials it purchases, or the intended presence of these materials in any of its products.
- Pall Medical does not specify, intentionally add or have any knowledge of the use of human origin materials including blood or plasma derivatives, in the raw materials it purchases, or the intended presence of these materials in any of its products. However, although Pall Medical takes reasonable precautions to maintain the cleanliness of its products, Pall Medical cannot exclude the possibility of the presence of individual cells originating from human or environmental contact prior to supply of materials to Pall Medical or during the manufacturing and packaging processes, but Pall Medical does not test for them.
- Pall Medical membranes and filters do not knowingly contain materials of direct animal origin i.e. animal parts, tissues, or body fluids or derivatives. They are not known to be present in the raw materials nor are they intentionally added in the manufacturing process.
- Pall Medical membranes and filters do not knowingly contain adjuvants such as mould release agents. They are not known to be present in the raw materials nor are they intentionally added in the moulding or manufacturing processes.

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- Conflict Minerals as defined below:
  - Tantalum (derived from columbite-tantalite)
  - Tin (derived from cassiterite)
  - Tungsten (derived from wolframite)
  - Gold

  and their derivatives when originating from the Democratic Republic of Congo, Angola, Burundi, the Central African Republic, Congo, Rwanda, Sudan, Uganda, the United Republic of Tanzania or Zambia, are not known to be present in the raw materials nor are they intentionally added in the manufacturing processes.
- Pall Medical does not specify, intentionally add or have any knowledge of the use of other (non-human or non- animal) non-viable biological substances in the raw materials it purchases, or the intended presence of these materials in any of its products.
- Substances listed below are not known to be present in the raw materials nor are they intentionally added in the manufacturing processes:
  - 2-MCBT and 2-MBT
  - 4-Nitrotoluene
  - Substances listed in 96/62/EC and TPCH
  - Alkyl phenols and their ethoxylates
  - Allergens per EU Directive 2003/89 Annex IIa or other known allergens
  - Azo colourants and dyes
  - Asbestos and asbestos fibre
  - Anthracene and its compounds
  - Benzophenones
  - Structural analogues of BPA
  - Bromine or brominated compounds
  - Butylated hydroxy toluene
  - Chlorine or chlorinated compounds
  - Cleaning agents (products are not washed or cleaned during production)
  - Colourants and inks other than those visibly present in or printed on housing or other components.
  - DEHP, DIBP, BBP AND DBP
  - Other phthalates of concern
  - Dimethyl fumarate
  - Dinitrobenzenes
  - Dioxins and cogeners including polychlorinated and polybrominated dioxins and dibenzodioxins (PCDD and PBDD)
  - Furans and cogeners including polychlorinated and polybrominated furans and dibenzofurans (PCDF and PBDF)
  - Flame retardants (halogenated and non-halogenated)
  - Substances derived from Genetically Modified Organisms
  - Hazardous Air Pollutants
  - Heavy metals and their compounds

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- Hydrazine
- Iso and di-isocyanates
- Jatropha derived substances
- MCCPs
- Metals in ink
- Microplastics (any type of plastic fragment used as a raw material that is less than 5 mm in length)
- Natural rubber latex or latex derivatives in the product or packaging
- Nitrosamines
- Organotin compounds
- Ozone depleting substances.
- PBT and vPvB substances
- PFAS
- Non-Phthalate plasticizers
- Pharmaceutical components known to be at risk for melamine contamination.
- Polycyclic aromatic hydrocarbons
- Polystyrene (all types) in product or packaging
- PVC in product
- Radioactive substances
- Recycled materials, post-consumer or other source
- SCCPs
- Sensitizers such as rosin, colophony, R42 and R43
- Silicone containing oils, release agents or sprays.
- Styrene
- Substances derived from micro-organisms (not GMO)
- Thiurams
- Toluene

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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SECTION 4 - First Aid Measures

4.1 First aid measures

Always address any contaminants present on the 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 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 membrane as supplied.

SECTION 5 - Fire Fighting Measures

5.1 Extinguishing media

Select an extinguish medium suitable for surrounding / working environment.

For filter set alone use dry chemical, CO_2, water spray (fog) or foam.

5.2 Specific Hazards

Hazardous thermal decomposition products: CO, CO_2, acrid smoke,

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.

SECTION 6 - Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

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

For used filters always address any contaminants present on the product as the result of use.

6.2 Environmental precautions

For unused product, 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.

6.3 Spillage containment and cleaning up.

For used product, use clear-up, containment and appropriate PPE measures related to the product being filtered and the materials of construction detailed in Section 3.

Care should be taken to consider the nature of any contamination on the product as the result of use and suitable PPE employed for handling medical waste. **See section 13 for disposal requirements.**

SECTION 7 – Handling and Storage

7.1 Handling

In the received condition, special protective equipment is not needed during handling and normal use of these products. However, gloves are recommended to prevent contamination of the product and maintain cleanliness. Handling of used product must take into account the nature of potential contaminants.

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 hygiene practices. Eating, drinking and smoking are generally prohibited in areas where this product is handled, stored or processed – exceptions are made on the guidance of local medical advice. Staff must follow standard work-place hygiene before eating, drinking or smoking after using this product. Wear gloves to prevent contamination of the membrane and maintain cleanliness of the unused product.

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7.2 Storage

The article is supplied dry, without the presence of any preserving fluid. Store in clean, dry conditions suitable for a medical device.

Handle with care to avoid damage.

Do not expose to direct sunlight during storage, 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 - do not use if damaged. Membrane can be damaged if roughly handled – particularly at sub-zero temperatures. Thermal shock by quickly raising the temperatures from sub-zero should be avoided.

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

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

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

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SECTION 9 - Physical and Chemical Properties

Appearance:	Disposable filter/membrane
Physical state:	Solid
Colour:	White
Solubility:	Insoluble in water.
Auto-ignition temperature:	N/A
Sensitive to shock:	Mechanical / thermal shock can result in damage.

SECTION 10 – Stability and Reactivity

Reactivity:	The product is stable under the recommended conditions of use and storage.
Chemical Stability:	The product 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 hot surfaces or other conditions that soften, swell or adversely affect the product or its materials of construction. Do not allow fluids to freeze on the product. Incompatible Materials: Strong Acids, alkalis and oxidising Agents (e.g. Perchloric Acid, nitric acid),
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 product as supplied. Consult SDS of the product being filtered for specific advice and recommendations.

11.1 Acute Toxicity

Mutagenicity / Carcinogenicity / Reproductive Toxicity / Teratogenicity: No known concern

Aspiration Hazard: Not applicable.

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

11.2 Chronic health effects

No known significant effects or critical hazards.

Carcinogenicity: No specific test data available, no evidence for hazardous properties

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SECTION 12 - Ecological Information

Pall Medical products are 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:

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.
Unused as supplied product: Disposal should be in-line with national legislation and local regulatory requirements for the materials present. Unused filter/membrane may be used as landfill.

Used product should be disposed of as clinical waste due to the nature of the contaminants as a result of use. Therefore, used products may be classified as hazardous – clinical waste.
Dispose of waste via a licensed waste disposal contractor.

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Packaging

Bagging: 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 landfill should only be considered where re-cycling is not feasible.

SECTION 14 - Transport Information

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

SECTION 15 – Change History

Rev number	Description of change
AA	New PSDI
AB	General review without changes only alignment of rev numbers and copyright date

Notice to Reader

To the best of our knowledge, the information contained herein is accurate. However, Pall Medical assumes no 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

Part numbers:

65750

65754

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