PRODUCT SAFETY DATA INFORMATION

Date: 25 March 2024

Data Sheet Number: PSDI Polypropylene melt blown membranes
Revision: 1

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Pall Medical polypropylene melt blown 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 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 Medical's published recommended use conditions.

These membranes are only intended for use in applications or for inclusion in devices which do not pose any risk of bioavailability of any residual chemicals present in the polymer membrane.

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

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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.

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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
Polypropylene	9003-07-0	100%

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 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. **With the possible exception of Toluene CAS 108-88-3 and DBP CAS 84-74-2 which may be present in trace amounts from raw materials or processing,** substances included in the list are not known to be present in the raw materials nor are they intentionally added in the manufacturing processes.

  These articles 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.

  Pall Medical cannot at this time confirm that the residual level of the substances listed above would result in the indirect exposure of an individual to levels above their exposure threshold due to the wide range of migration scenarios that could be encountered in their use, however, inhalation or ingestion of 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 will continue to monitor updates to Proposition-65. Should you have any questions related to the information provided by Pall Medical please do not hesitate to contact your local Pall Medical Customer Services department.

- 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 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 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.
- Nitrosamines and related compounds (Nitrous Acid, secondary, tertiary, and quaternary amines, nitrite salts, sodium azide, amine reagents or solvents, nitrate salts that may contain nitrite impurities), are not

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known to be present in the raw materials nor are they intentionally used in the formulations and manufacturing processes. These processes do not include the use of or the known generation of nitrogen oxides or amines, nor do any of the processes include fermentation steps. There are no specific sourcing controls other than those mentioned above.

- 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.
- Trace additives will be present in the polypropylene. Anti-oxidants are present for stabilisation purposes.

- 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
  - Bisphenol A (BPA)
  - 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 and BBP
  - Other phthalates of concern
  - Dimethyl fumarate
  - Dinitrobenzenes

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- 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
- 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
- Organotin compounds
- Ozone depleting substances.
- PBT and vPvB substances
- PFAS or other fluorinated compounds
- 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 or packaging
- 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

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

None identified.

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.

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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.

For used product, 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 used product and place in a designated, labelled waste container.

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 filter/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.

Please also consult Pall 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:	All components Insoluble in water.
Auto-ignition temperature:	Not applicable
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. is based on typical information for the material types named above. This information has not been determined specifically for Pall Medical products.

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.

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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.

Packaging

Support core: Polypropylene

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
1	New PSDI.

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:

40486	40501	40502
40520	42001	42003
42004	42005	45151
45162	45163	45173
65746	65916	80900
80901	80902	80905
80906	80907	80911
80912	80913	80915
80916	80917	80918
80971	114-0065	42000B1
42002B1	5NC110	5NC11044
5NC18044	5NC80-12.75	5NC8044
AM0709N	AP0911S	BSP0744
FH00191	FP0321250L01010	FP0321250L01012
FP0401600U01014	FP0572100U01013	HDC0447
HDC0609	P0180800L01	P0201250L01
P0220700U01	P0230300L01	P0250950B02
P0250950B07	P0250950B08	P0250950B09
P0250950B10	P0251700L01	P0270550L01
P0321250L01	P0401600U01	P0401900L01
P0402750L01	P0402750U01K	P0500850L01
P0500950L01	P0572100U01	P0602830L01
P0602830U01	P0852000L01	P0900017L01
P0900020L01	P0900025L01	P0900030L01
P0900037L01	P0900065L01	P0901700L01
P0920070L01	P0950800L01	P1000030L01
P1000050L01	P1000050L02	P1000100L01
P1050200L01	P1050200L02	P1050350L01
P1050450L01	P16R3942A44	PPR-5NC110
PPR-5NC11044	PPR-5NC18044	PPR-5NC8044
PPR-P16R3942A44	PPR-P17R5053A44	S80900
S80903	S80904	S80911
S80912	SP0230300L01	SP0230300L0115
SP0230300L0126	SP0270550L0127	SP0270550L0128
SP0270550L0129	SP0270550L0131	SP0270550L0133
SP0321250L0130	SP0401600U001	SP0401600U01003
SP0401600U01011	SP0572100U01	SP0572100U01004
SP0572100U0119	SP0602830L01001	SP0900020L01

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