

PRODUCT SAFETY DATA INFORMATION

Date: 20 May 2019

Data Sheet Number: PSDS2019/5/a Revision: 0

SECTION 1 – Product Identification

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

Example Product name(s): Vivid™ Plasma Separation GF, Vivid™ Plasma Separation GX, and Vivid™ Plasma Separation GR membranes

Example Part Number(s): T9EXPPA0200S00R, T9EXPPA0200S00A and T9EXPPA0200S00X
T9PA200W900G, T9PA200W900R, T9PA200W900X

The VIVID Plasma Separation products detailed above are intended for plasma separation of whole blood.

Supplier: Pall Corporation, San Diego, USA.

Country of Origin: USA

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

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

The VIVID Plasma Separation membranes detailed in Section 1 are comprised of the following materials:

Material Name	CAS Number
Polysulfone (PS) membrane GF, GX and GR variants specifically have a low binding surface treatment to minimize red blood cell haemolysis	Pall proprietary information

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Note: Bisphenol-A (BPA) is a monomer for the production of polysulfone material and therefore the product may contain trace levels of BPA. Users are advised to ensure this is considered in assessing the suitability of this material for their use.

N-methyl-2-pyrrolidone (NMP) is used in contact with the material during manufacture and the user should satisfy themselves that any trace residual levels of this solvent do not impact their use.

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 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 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.

The above Pall Medical separation membranes do not employ natural rubber latex, or latex derivatives in their construction.

SECTION 4 - First Aid Measures

4.1 First aid measures

Always address any contaminants present on separation membranes 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 therefore 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.

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4.2 Key symptoms and effects

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

SECTION 5 - Fire Fighting Measures

5.1 Extinguishing media

Select an extinguish medium suitable for surrounding / working environment.

For Vivid separation membrane alone use dry chemical, CO₂, water spray (fog) or foam.

5.2 Specific Hazards

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

For the Vivid separation membrane alone: No specific fire or explosion hazard. Hazardous thermal decomposition products: CO, CO₂, Acrid Smoke.

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.

SECTION 6 - Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

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

For used VIVID Plasma Separation membranes always address any contaminants present on the membrane as the result of use.

6.2 Environmental precautions

For VIVID Plasma Separation unused membranes; 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 separation membranes, using clear-up, containment and appropriate PPE measures related to the product being filtered and the materials of construction detailed in Section 3.

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6.3 Spillage containment and cleaning up

Use suitable equipment to collect the membrane material and place in a designated, labelled waste container.

Care should be taken to consider the nature of any contamination on the separation membrane as the result of use and suitable PPE employed for handling medical waste.

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 separation membrane.

VIVID Plasma Separation products are for professional use only.

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

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 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 separation membrane and maintain cleanliness of the unused separation material.

7.2 Storage

VIVID Plasma Separation membranes are 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.

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- Ensure careful handling to avoid physical damage. Ensure shipping bag and packaging 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).

Please also consult the Pall 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 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 required to ensure separation membrane remains clean during installation.

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

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

SECTION 9 - Physical and Chemical Properties

Appearance: Disposable separation membrane sheets (dimensions 8" x 11") or roll form

Physical state: Solid

Colour: White

Solubility: Insoluble in water

Sensitive to shock: Mechanical / thermal shock can result in damage to the separation membrane

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SECTION 10 – Stability and Reactivity

Reactivity:	The separation membrane is stable under the recommended conditions of use and storage.
Chemical Stability:	The separation 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 separation membrane or its materials of construction. Do not allow fluids to freeze on the separation membrane.
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 separation membrane as supplied. Consult SDS details of the product being filtered for specific advice and recommendations.

11.1 Acute Toxicity

Based on typical information for the material type named, this information has not been determined specifically for Pall Medical separation membranes.

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

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11.2 Chronic health effects

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

Carcinogenicity: No specific test data available.

SECTION 12 - Ecological Information

Pall Medical separation membranes 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:

Unused as supplied separation membranes: Disposal/handling of the un-used VIVID Plasma Separation membranes should be in-line with national legislation and local regulatory requirements for the materials present. Unused separation membranes may be used as land-fill in many countries – please check with local regulations and guidelines.

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.

Used VIVID Plasma Separation membranes should be disposed of as clinical waste due to the nature of the contaminants on the membranes as a result of use. Therefore, used VIVID Plasma Separation separation membranes may be classified as hazardous – clinical waste.

Packaging

Bagging: Plastic

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.

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SECTION 14 - Transport Information

Clean and un-used separation VIVID Plasma Separation membranes, supplied in their original packaging, are not classified as dangerous goods under ADR, RID, IMDG or IATA regulations.

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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:

T9EXPPA0200S00%

T9EXP%%200R###%

T9EXP%%300R###%

T9PA200W900%

Where:

(%%) indicates unique Pall identifier

(###) indicates unique filter size

(%) indicates product variant (i.e. GF, GR, or GX)