Pall Corporation

Status CURRENT

PRODUCT SAFETY DATA INFORMATION

Date: 23rd March 2022

Data Sheet Number: PSDI Cytosep Membrane Revision: 1

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Pall Medical Cytosep membrane

Product name(s): CytoSep® 1660, 1662 and 1663

Part Number(s): See appendix 1

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 the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)..

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

Filter assembly (All codes)

Material Name	CAS Number	Percentage composition
Cellulose	9004-34-6	45
Borosilicate glass	65997-17-3	<30
Polyester	25038-59-9	<30

These products are not known to contain BADGE, NOGE, or BFDGE.

Trace additives will be present in the plastic components.

There are no current SVHC substances known to be present in the finished articles above 0.1%.

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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.

There is no natural rubber latex, or latex derivatives in the construction.

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. Plastics may contain 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 for human food and Regulation (EU) 722/2012 concerning medical devices manufactured using tissues of animal origin, in Article 4, specifically excludes tallow derivatives provided they have been processed under conditions at least as rigorous as those stated in Section 3 of Annex 1 as shown below:
>
> - Trans-esterification or hydrolysis at not less than 200 °C for not less than 20 minutes under pressure (glycerol, fatty acids and fatty acid esters production),
> - Saponification with NaOH 12 M (glycerol and soap production)
> - Batch process: at not less than 95 °C for not less than 3 hours,
> - Continuous process: at not less than 140 °C, under pressure for not less than 8 minutes or equivalent,
> - Distillation at 200 °C.

The components in the membranes we supply have been processed with one of 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

Federal regulations:

OSHA Hazard Communication Standard 29 CFR 1910.1200: This material is not a “health hazard” and/or a “physical hazard” as determined when reviewed according to the requirements of the Occupational Safety and Health Administration 29 CFR Part 1910.1200 “Hazard Communication” Standard.

Environmental regulations:

SARA Title III: This product does not contain any toxic chemical(s) subject to the reporting requirements under Sections 302, 304, 313, (40 CFR 372) of Title III of the Superfund Amendments and Reauthorization Act of 1986. Sections 311 and 312 (40 CFR 370) may apply (delayed hazards) when dust is created.

Toxic Substances Control Act (TSCA): Not required to be listed on the TSCA inventory.

State regulations:

California Proposition 65: **WARNING**: This product can potentially expose you to the chemical glass wool fibers (inhalable and biopersistent), which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.

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:	In case of eye contact flush with running water for 15 minutes. If discomfort continues, seek medical attention.
Inhalation:	Dust fibers from slitting and cutting operations can cause temporary, mild irritation to the respiratory tract. Remove individual to fresh air. If irritation persists, seek medical advice.
Skin Contact:	If irritation occurs, remove contaminated clothing and shoes; wash skin with soap and water. Wash clothing before reuse.
Ingestion:	Dust fibers from slitting and cutting operations can cause temporary, mild irritation. Eliminate dust fiber from any location where ingestion may occur. If irritation persists for more than 24 hours, 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 as supplied.

SECTION 5 - Fire Fighting Measures

5.1 Extinguishing media

All standard agents may be used including water, carbon dioxide foam, and dry powder.

5.2 Specific Hazards

Hazardous thermal decomposition products: Dense smoke and toxic gases may be generated

5.3 Advice to Fire Fighters

Wear self-contained breathing apparatus, protective clothing, and extinguish fire by cooling the material with water spray. If fire was caused by electrical short circuit, it cannot be put out with water.

SECTION 6 - Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Minimize airborne dust. Pick up large pieces. Vacuum dust. If sweeping is necessary, use a dust suppressant such as water.

6.2 Environmental precautions

Comply with state and local regulations for the disposal of glass products. If you are unsure of the regulations or have caused any environmental pollution, contact your local public health department or the local office of the Environmental Protection Agency (EPA).

6.3 Spillage containment and cleaning up

Care should be taken to consider the nature of any contamination on the 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

Use appropriate personal protective equipment for the working environment (See Section 8).

Follow good hygiene practices. Staff must follow standard work-place hygiene before eating, drinking or smoking after using this product. Wear gloves to prevent contamination and maintain cleanliness of the unused membrane.

7.2 Storage

Prevent product contamination, typically by keeping in original packaging or equivalent and stored in a cool, ventilated warehouse, away from incompatible materials and ignition sources.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

Good general ventilation should suffice to control worker exposure to any airborne contaminants.

8.2 Exposure controls

Skin protection:

None required. Wear impervious gloves as needed to prevent skin contact.

Eye protection:

If contact with eyes is possible during processing, safety glasses are recommended.

Respiratory protection:

None normally required. An approved dust respirator meeting 42 CFR Part 84 standards should be worn if there is a high dust concentration in the air.

Exposure Guidelines:

Dust should be considered a nuisance dust and follow ACGIH TLV and OSHA PEL (Section 3).

SECTION 9 - Physical and Chemical Properties

Appearance/physical state:	Solid, white paper-like material
Colour:	White
Solubility:	Insoluble in water
Specific gravity:	1.27-1.61
Flammability:	Combustible solid
Auto-ignition temperature:	400-500°F (204.4-260°C)
Sensitive to shock:	Mechanical / thermal shock can result in damage to the filter

SECTION 10 – Stability and Reactivity

Reactivity: Non-reactive.

Chemical Stability:	Stable under normal conditions of temperature and pressure.
Hazardous Polymerisation:	Polymerisation will not occur under recommended conditions of use and storage.
Other hazardous reactions:	Under normal conditions of storage and use, no hazardous reactions will occur.
Conditions to Avoid:	None
Incompatible Materials:	None
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 membrane as supplied. Consult SDS details of the product being filtered for specific advice and recommendations.

Likely Routes of Exposure:	See First Aid Measures above (section 4)
Acute Toxicity:	Non-toxic in general circumstances. If ingested heavily may cause physical damage to human body. Ingestion is not recommended.
Chronic Toxicity:	Not applicable
Toxicity (LD50):	Not determined
IARC:	Group 3: Not classifiable as to its carcinogenicity to humans Biopersistent glass microfiber.
OSHA:	Suspected human carcinogen, if in inhalable form.
NTP:	Exposure to inhaled and biopersistent glass microfiber dust is reasonably anticipated to be a human carcinogen.

SECTION 12 - Ecological Information

Ecotoxicity:	Product has not been evaluated for ecotoxicity.

SECTION 13 - Disposal Information

Refer to exposure controls/personal protection (section 8) when disposing of material for safe handling. Do not dump into sewers, on the ground, or into any body of water. Waste is not hazardous as defined by the Resource Conservation and Recovery Act (RCRA). Dispose of according to all federal, state and local relevant laws and regulations. If you are unsure about the regulations, contact your local public health department or the local office of the Environmental Protection Agency (EPA).

Used 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 membranes may be classified as hazardous – clinical waste.

Packaging

Bagging: Plastic (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

General: Not regulated.

U.S. DOT: Not classified as a hazardous material.

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

Part numbers:

BSPCY60-02

BSPCY601

BSPCY602030P

BSPCY606

BSPCY60PK

BSPCY6201

BSPCY6202

BSPCY6206

BSPCY6215

BSPCY622030P

BSPCY6265

BSPCY62PK

BSPCY6302

BSPCY6316P

BSPCY632030

S70002

S70004

S70005