

PRODUCT SAFETY DATA INFORMATION

Date: 08th March 2019

Data Sheet Number: PSDS2019PMED05 Revision: 1

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Pall Medical Intervene®, disposable filter cartridges, each employing a glass fibre on a polyester substrate (Pallflex®) hydrophobic filter medium within an acrylic body.

Product name(s): Intervene™ Gas Filter

Part Number(s): 8004022

The filters detailed above are intended for patient protection in medical applications.

- Gas Insufflation in Minimal Invasive Surgery – MIS
- Filtration of Medical Gases for example Oxygen, Carbon dioxide (CO₂)
- Vacuum Protection

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 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.

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SECTION 3 - Materials of Construction

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

Material Name	CAS Number
Glass Fibre (Pallflex®)	Pall proprietary information
Polyester Substrate	CAS: 25038-59-9
Modified acrylic copolymer housing body	Polymer supplier proprietary information

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

Trace additives will be present in the plastic components.

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the article.

There are no current 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 Diisobutyl 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.

Pall Medical filters do not employ natural rubber latex, or latex derivatives in their construction.

These products (see appendix 1) do not contain animal materials (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:

Pall filters for healthcare and laboratory applications may utilise components which are fabricated from plastic resins containing animal-derived additives at trace levels such as tallow-derived substances. Please be advised that tallow-derived additives are not considered specified BSE risk materials according to the current revision of the U.S. Code of Federal Regulations, Title 21 of part 189.5. Furthermore, the CPMP's *Note for guidance on minimising the risk of transmitting animal spongiform encephalopathies via human and veterinary medicinal products* (EMA410/01 rev 3) gives 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).

SECTION 4 - First Aid Measures**4.1 First aid measures**

Always address any contaminants present on the filter 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 filter as supplied.

SECTION 5 - Fire Fighting Measures**5.1 Extinguishing media**

Select an extinguish medium suitable for surrounding / working environment.

For filter 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. Release of glass fibres as the result of decomposition.

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

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 filters in the unused condition as supplied.

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

6.2 Environmental precautions

For unused filter modules, 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 modules, 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 material and place in a designated, labelled waste container.

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

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 cartridge and maintain cleanliness of the unused filter.

7.2 Storage

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

The article is supplied dry, without the presence of any preserving fluid.

Store in a cool, clean environment.

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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.

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).

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 recommended to ensure filter remains clean during installation.

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

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

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SECTION 9 - Physical and Chemical Properties

Appearance:	Disposable filter
Physical state:	Solid
Colour:	Clear / White outer housing with white filter material
Solubility:	Insoluble in water Acrylic components readily soluble in esters, ketones and chlorinated hydrocarbons
Auto-ignition temperature:	Acrylic components: 440 °C (830 °F), decomposition begins at 250 °C (482 °F) Glass Fibre – Not known
Sensitive to shock:	Mechanical / thermal shock can result in damage to the filter

SECTION 10 – Stability and Reactivity

Reactivity:	The filter is stable under the recommended conditions of use and storage.
Chemical Stability:	The filter 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 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.

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SECTION 11 - Toxicological Information

The information in this section contains generic advice and guidance in respect of the unused filter as supplied. Consult SDS details of the product being filtered for specific advice and recommendations.

11.1 Acute Toxicity

Irritation/Corrosion/Sensitisation: **There is no data available**

Mutagenicity / Carcinogenicity / Reproductive Toxicity / Teratogenicity: **There is no data available**

Aspiration Hazard: Not applicable for un-used filter. **There is no data available**

Potential acute health effects:

Eye contact : No known significant effects or critical hazards

Inhalation : None under normal conditions of use or storage. If activities that create dust are conducted, inhalation of dusts can cause nose, throat and upper respiratory tract irritation. Symptoms include coughing, sneezing and throat irritation.

Skin contact: Skin irritation possible

Ingestion : No known significant effects or critical hazards.

11.2 Chronic health effects

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

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

SECTION 12 - Ecological Information

Pall Medical filters are not expected to degrade in contact with soil or water under ambient conditions.

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SECTION 13 - Disposal Information

The information in this section contains generic advice and guidance.

Product

Methods of disposal:

Unused as supplied filters: Disposal/handling of the un-used filters should be in-line with national legislation and local regulatory requirements for the materials present. Unused filter cartridges may be used as land-fill.

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 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.

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 land-fill should only be considered where re-cycling is not feasible.

SECTION 14 - Transport Information

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

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Notice to Reader

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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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