Pall Corporation

PRODUCT SAFETY DATA INFORMATION

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SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Pall Medical MIRUS™ Filter platform product variants

Product name(s): MGF; U50

Part Number(s): See appendix 1

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

- Filtration of medical gases as specified by customer e.g. in
  - Anesthesia
  - Intensive care ventilation
  - Application of volatile anaesthetic gases

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

Material Name	CAS Number
Polypropylene homopolymer housing	9003-07-0
Resin bonded glass fibre medium	supplier proprietary information
Thermoplastic polymer monitoring port cap - EPDM rubber dispersed in Polypropylene matrix	9003-07-0 and 25038-36-2
Polyolefin Hotmelt	supplier proprietary information
Blue and yellow colorant	9003-07-0 otherwise supplier proprietary information
Polyethylene bag	9002-88-4

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 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.

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 Medical products 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. Pall Medical products may utilize components in the fluid pathway which are fabricated from plastic resins containing 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 plastics raw materials we purchase 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

WARNING:

This product can expose you to glass wool fibres including special purpose glass fibres of respirable size which are known in the State of California to cause cancer.

For more information go to www.P65Warnings.ca.gov

These products placed on the market in the State of California by Pall are not intended for 'consumer' sale, but, are for professional or industrial use. Therefore, the only anticipated exposure to these items would be through 'occupational exposure' which does not require mandatory labelling of all articles. In line with the 'Questions and Answers for business' (dated August 2017) on the labelling requirements – Q41 – this SDS conveys this warning for occupational exposure.

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

Hazardous thermal decomposition products: CO, CO_2, Acrid Smoke, aldehydes, Acrolein, Formaldehyde, Sulphur Dioxide, H_2S, low molecular weight and other hydrocarbons

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 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 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 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.

SECTION 9 - Physical and Chemical Properties

Appearance: Disposable filter

Physical state: Solid

Colour: Blue outer housing with white filter material and yellow monitoring port cap

Solubility: All components Insoluble in water

Auto-ignition temperature: Polypropylene >300°C

Glass fibre media: N/A

Tethered cap: Not established

Housings: Not established

Cured hotmelt: Not established

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

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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 hot surfaces or other conditions that soften, swell or adversely affect the filter or its materials of construction.

Incompatible Materials: Strong Oxidising Agents (e.g. Percloric Acid, nitric acid, fluorine), alkali metals, strong alkalis and reducing agents, organic acids

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 filter as supplied. Consult SDS details of the product being filtered for specific advice and recommendations.

11.1 Acute Toxicity

Materials of construction have been tested in accordance with ISO10993-1: 2009 and complied with requirements as laid out in sections 6.2.2.2 on cytotoxicity, 6.2.2.3 on sensitisation, and 6.2.2.4 on irritation or intracutaneous reactivity

Mutagenicity / Carcinogenicity / Reproductive Toxicity / Teratogenicity: No known concern for the materials of construction of the filter as supplied (new and unused)

Aspiration Hazard: Not applicable for un-used filter.

Potential acute health effects: No known significant effects or critical hazards for the unused filter as supplied.

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

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SECTION 12 - Ecological Information

Pall Medical filters 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 filters: Disposal/handling of the un-used filters should be in-line with national legislation and local regulatory requirements for the materials present. As stated in section 3.1, unused filters contain bonded glass fibres which may be released if disposal of unused product occurs without being treated as clinical waste.

Warning:

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 filters 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/polyester)

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 filter, supplied in its original packaging, is not classified as dangerous goods under ADR, RID, IMDG or IATA regulations.

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.

APPENDIX 1

PALL PART NUMBER	PRODUCT FAMILY	PRODUCT DESCRIPTION
MGF50	Medical Gas Filter	Medium Size Gas Filter
MGF1	Medical Gas Filter	Medium Size Gas Filter with monitoring port
MF1	MIRUS	MIRUS Filter
U50	Ultipor® 50	Breathing System Filter for patient side or machine side application