Pall Corporation

PRODUCT SAFETY DATA INFORMATION

Date: 13 December 2022

Data Sheet Number: **Pall Laparoshield Laparoscopic Surgical Smoke Filter** Revision: 1

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers **Pall Laparoshield™ Laparoscopic Surgical Smoke Filter Family** platform variants.

Product name(s): **Pall Laparoshield™ Laparoscopic Surgical Smoke Filter**

Part Number(s): LSF1 (18" length tube variant with roller clamp)
LSF2 (½" length tube variant)

The devices detailed above are intended for single patient use during any minimally invasive surgery involving insufflation, electrocautery, laser or sonic scalpel use. The filter allows the surgeon to rapidly clear smoke from the visual field during laparoscopic surgery without loss of pneumoperitoneum. The filter has been designed to retain bacteria and viruses and reduces the by-products of combustion which include odour, volatile gases and smoke

For further information on Pall products, please visit Pall at https://www.pall.com/en/about-pall.html

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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

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

Filter assembly (All codes)

Material Name	CAS Number
Polyester (PBT)	80595-68-2
Ceramic fibre with polyester laminate and acrylic binder	Pall proprietary information
PolyTetraFluoroEthylene (PTFE)	9002-84-0
Activated Carbon	64365-11-3
Acrylic Fibre	63231-45-8
Polypropylene (PP)	9003-07-0
EthyleneVinylAcetate (EVA)	24937-78-8
PolyVinylChloride (PVC)	9002-86-2
AcrylonitrileButadieneStyrene (ABS)	9003-56-9

Device Components:

Material Name	Product codes	CAS Number
Filter Bag outer covering	LSF1 LSF2	80595-68-2
Filter Bag Prefilter	LSF1 LSF2	Pall proprietary information
Filter Bag Adsorbent (encapsulated)	LSF1 LSF2	64365-11-3 (63231-45-8 / 9003-07-0)
Filter Bag Film Layer	LSF1 LSF2	24937-78-8
Tubing	LSF1 LSF2	9002-86-2
Male Luer Connector with locking collar	LSF1 LSF2	9003-56-9 / 9003-07-0
Rollerclamp	LSF1	9003-56-9

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 membranes and filters 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 Medical 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.
Furthermore, the Committee for Proprietary Medicinal Product (CPMP)'s *Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathies via human and veterinary medicinal products* (EMA410/01 rev 3) and Regulation (EU) 722/2012 **EEC** concerning medical devices manufactured using tissues of animal origin in Article 4, give specific consideration to tallow derivatives and states they are unlikely to be infectious or can be excluded due to the rigorous processing steps used during their manufacture examples of which are:

- Trans-esterification or hydrolysis at not less than 200 ℃ 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 ℃ for not less than 3 hours,
- Continuous process: at not less than 140 ℃, under pressure for not less than 8 minutes or equivalent,
- Distillation at 200 ℃.

Pall Medical continually 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.

The device IFU contains a caution statement as detailed below:
The PVC tubing contains di(2-ethylhexyl) phthalate (DEHP). Precautions should be taken to limit long-term exposure to DEHP in certain groups of patients who, based on animal data, may be at risk of adverse effects on reproductive and developmental processes. These are male newborns, infants and young children, peripubertal males and pregnant or nursing women. Medical procedures should not be avoided however, as the benefits outweigh any possible health risks associated with DEHP exposure. Please refer to current literature to make an informed decision.

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 set alone use dry chemical, CO2, water spray (fog) or foam.

5.2 Specific Hazards

None known

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/filter set

Physical state: Solid

Colour: Various

Solubility: All components Insoluble in water

Auto-ignition temperatures:

Polyester (PBT)	Typically >400°C
Ceramic fibre with polyester laminate and acrylic binder	Typically >400°C
PolyTetraFluoroEthylene (PTFE)	Typically >400°C
Activated Carbon	Typically >400°C
Acrylic Fibre	Typically >300°C
Polypropylene (PP)	Typically >300°C
EthyleneVinylAcetate (EVA)	Typically >300°C
PolyVinylChloride (PVC)	Typically >400°C
AcrylonitrileButadieneStyrene (ABS)	Typically >300°C

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 hot surfaces or other 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:	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 filter 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 filters

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

Note that the finished devices have been tested to the relevant sections of ISO 10993 with all acceptance criteria met

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. Unused filters 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 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.