PRODUCT SAFETY DATA INFORMATION

Date: 17/11/25

Data Sheet Number: PSDI_ **Laparoshield Laparoscopic Surgical Smoke** Family Revision: AG

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Pall Medical Laparoshield™ Laparoscopic Surgical Smoke Filter Family platform product variants. Unless specified in one of the following sections, all statements refer to all the in-scope part numbers.

Part Number(s): See appendix 1

The filters 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 Medical products, please visit www.Cytiva.com/pallmedical

SECTION 2 - Hazards Identification

Product definition: Article.

These products are not classified as hazardous according to current versions of UN Recommendations on the Transport of dangerous goods: Model regulations, GB Chemical classification, labelling and packaging (CLP) or European CLP/GHS Regulation 1272/2008 (current ATP)

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 products detailed in Section 1 are comprised of the following main materials:

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
Ethylene-vinyl acetate (EVA)	24937-78-8
Polyvinyl Chloride (PVC)	9002-86-2
Acrylonitrile Butadiene Styrene (ABS)	9003-56-9

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Regulations, Acts, Guidances, Notifications, Directives and miscellaneous substances of concern lists

Pall Medical continually monitors the Regulations, Acts, Guidances, Notifications and Directives listed below and in the event of a relevant update occurring, this PSDI will be updated and published to the website. PSDIs will not be updated simply to show reviews have occurred. The substances discussed below are not tested for by Pall Medical.

- Substances included in the REACH Candidate List of Substances of Very High Concern are not known to be present at a concentration > 0.1%
- Substances listed in the REACH restricted substances list (Annex XVII) with relevant restrictions or the REACH authorised substances list (Annex XIV) are not known to be present in the raw materials nor are they intentionally added in the manufacturing process.
- The State of California requires 'clear and reasonable warnings' in respect of amounts of specific chemicals in the consumer products they purchase, in homes or workplaces or that are released into the environment. The aim of the warnings is to protect against chemicals known by the State of California to cause cancer, birth defects or reproductive harm. The list of substances of concern, their form, and/or the exposure level above which notification for each substance is required (or 'safe harbor level') being that published by the State and known as the Proposition-65 list. **This material can potentially expose users to the substances listed below which are known to the State of California to cause cancer and developmental toxicity.**

Substance	CAS#
Di (2-ethylhexyl)phthalate (DEHP) may be present in the polypropylene luer connector rotating hub *	117-81-7
Di-n-butyl phthalate (DBP) may be present in the polypropylene luer connector rotating hub *	84-74-2
Vinyl Acetate	108-05-4
Acrylonitrile	107-13-1
Styrene	98-83-9
1,3 Butadiene	106-99-0
Formaldehyde	50-00-0
Acetaldehyde	75-07-0
Carbon black	133-86-4

* See Note on page 6

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Pall Medical membranes and filters placed on the market in the State of California are not intended for 'consumer' sale but are for professional use. As the result of use they will be expected to be disposed of as 'hazardous waste' within an appropriate waste stream reflecting the contaminant present as the result of use. These articles are supplied in sealed bags and boxed and any direct contact with the materials of construction of those items is expected to be through 'occupational exposure', which does not require mandatory labelling of articles. Inhalation or ingestion of filters or sheet or roll membrane articles are considered unlikely scenarios. Also, as gloves are also recommended to be used when handling Pall Medical membranes and filters to maintain cleanliness of the product, skin contact is also considered an unlikely exposure scenario.

- Pall Medical does not specify, intentionally add or have any knowledge of the use of EU RoHS (also known as Directive 2002/95/EC and amendment 2015/863) or any other country RoHS listed materials in the raw materials it purchases, or the intended presence of these materials in any of its products.
- Substances of concern categories listed in the EU Waste Framework are not specified by Pall Medical in the raw materials nor are they intentionally added in the manufacturing processes, but Pall Medical does not test for them. Unused Pall filters are not to the best of our knowledge classified as hazardous waste. 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.
- Nanomaterials according to 2011/696/EU and nanomaterial forms of all other substances listed in this PSDI are not known to be present in the raw materials nor are they intentionally added in the manufacturing processes.
- Substances above 0.1 % (weight by weight) which are carcinogenic, mutagenic or toxic (CMR) for reproduction of category 1A or 1B in accordance with the current ATP to Part 3 of Annex VI to Regulation (EC) No.1272/2008 are not known to be present at a concentration > 0.1%.
- Substances having endocrine-disrupting (ED) properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in the article 59 of Regulation (EC) No. 1907/2006 or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 are not known to be present at a concentration > 0.1%,
- In May 2019 the Stockholm Convention moved to add perfluorooctanoic acid (PFOA) and/or PFOA-related compounds to its POPs Annex A, with the intention of restricting the use of PFOA and its related compounds to a limited range of applications within the ratifying countries. For example, European Commission Delegated Regulation 2020/784 and subsequent amendments to Regulation (EU) 2019/1021 regards PFOA, its salts and PFOA-related compounds. PFOA, its salts and PFOA related compounds are not intentionally used by Pall in the manufacturing processes of the above filters, nor are these substances known to be intentionally present in the raw materials that Pall employs or generated in the processes used to make those raw materials. Based on our PTFE supplier's information, they are not present above the current limit of detection. Based on our PTFE supplier's information and Pall's knowledge of the processes it employs in filter production, levels of PFOA and PFOA related compounds are not known to exceed the following:

  25 ppb PFOA
  1000ppb PFOA-related compounds

  The PTFE used may contain low levels of other PFAS as residuals. According to information provided by the PTFE supplier, PFHxS, PFCA or PFOS or any salts or related compounds are not used. They

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are not present above the current limit of detection. Testing of the membrane to determine levels of residual PFAS has not yet been conducted.

- The materials of construction and substances employed in making Pall Medical membranes and filters are not specified to have actively anti-microbial, anti-bacterial or other biocidal properties.
- Pall Medical does not specify, intentionally add or have any knowledge of the use of medicinal substances or combinations of substances that are absorbed by or locally dispersed in the human body from its suppliers and does not specify or have any knowledge of the use of such materials in the raw materials it purchases, or the intended presence of these materials in any of its products
- Pall does not specify, intentionally add or have any knowledge of the use of human origin materials including blood or plasma derivatives, in the raw materials it purchases, or the intended presence of these materials in any of its products. However, although Pall Medical takes reasonable precautions to maintain the cleanliness of its products, Pall Medical cannot exclude the possibility of the presence of individual cells originating from human or environmental contact prior to supply of materials to Pall Medical or during the manufacturing and packaging processes, but Pall Medical does not test for them.
- With the exception of the PVC tubing these products do not knowingly contain materials of direct animal origin i.e. animal parts, tissues, or body fluids or derivatives. They are not known to be present in the raw materials nor are they intentionally added in the manufacturing process. Stearate stabilizers added to the PVC grade in use are stated to have been manufactured using animal tallow as a starting substance (“tallow-derivatives”). Please be advised that bovine tallow-derivatives are considered low risk material for TSE/BSE according to the current revision of the U.S. Code of Federal Regulations, Title 21 Part 189.5 Substances Prohibited from Use in Human Food; Sub part B: Prohibited Cattle Material: Paragraph a7. Furthermore, the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) ‘Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products’ (EMA/410/01 Rev 3, 2011), and other international guidelines, gives specific consideration to tallow-derivatives and states that they are unlikely to be infectious if rigorously processed during their manufacture (for example, hydrolysis or transesterification, at not less than 200 °C under pressure for not less than 20 minutes). Our suppliers have stated that their raw materials have been processed under conditions at least as rigorous as these.
- Pall Medical membranes and filters do not knowingly contain adjuvants such as mould release agents. They are not known to be present in the raw materials nor are they intentionally added in the moulding or manufacturing processes.
- Nitrosamines and related compounds (Nitrous Acid, secondary, tertiary and quaternary amines, nitrite salts, sodium azide, amine reagents or solvents, nitrate salts that may contain nitrite impurities), are not known to be present in the raw materials nor are they intentionally used in the formulations and manufacturing processes. These processes do not include the use of or the known generation of nitrogen oxides or amines, nor do any of the processes include fermentation steps. There are no specific sourcing controls other than those mentioned above.
- Conflict Minerals as defined below:
    - Tantalum (derived from columbite-tantalite)
    - Tin (derived from cassiterite)
    - Tungsten (derived from wolframite)
    - Gold

  and their derivatives when originating from the Democratic Republic of Congo, Angola, Burundi, the Central African Republic, Congo, Rwanda, Sudan, Uganda, the United Republic of Tanzania or Zambia,

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are not known to be present in the raw materials nor are they intentionally added in the manufacturing processes.

- Pall Medical does not specify, intentionally add or have any knowledge of the use of other (non-human or non- animal) non-viable biological substances in the raw materials it purchases, or the intended presence of these materials in any of its products.
- Tris (nonylphenol) phosphite TNPP CAS 26523-78-4 may be present at a concentration of < 0.1%

  Note: DEHP, DIBP and DBP may be present due to the polymerisation catalyst system used to make the polypropylene base polymer used on the rotating luer hub. DBP and DEHP are impurities in diisobutyl phthalate (DIBP), which is a minor component of the catalyst system. Calculated estimates confirmed by polymer manufacturer testing of several resins indicate a potential total residual phthalate (all phthalates) content of less than 10-15 ppm (parts per million). Further testing with food simulants, per general conditions of use as established in European Union Regulation 10/2011/EC did not detect any phthalate migration at a detection sensitivity of 20 ppb (parts per billion) (0.02 parts per million or 0.02 mg/kg). A worst case estimate of the amount of DBP or DEHP that could potentially migrate from the resin is calculated to be less than 10 ppb (parts per billion) each in the polypropylene polymer.

- Substances listed below are not known to be present in the raw materials nor are they intentionally added in the manufacturing processes:
  - 2-MCBT and 2-MBT
  - 4-Nitrotoluene
  - Substances listed in **96/62/EC** and TPCH
  - Alkyl phenols and their ethoxylates
  - Allergens per EU Directive 2003/89 Annex IIa or other known allergens
  - Azo colourants and dyes
  - Asbestos and asbestos fibre
  - Anthracene and its compounds
  - Benzophenones
  - BPA
  - Structural analogues of BPA
  - Bromine or brominated compounds
  - Butylated hydroxy toluene
  - Chlorine or chlorinated compounds
  - Cleaning agents (products are not washed or cleaned during production)
  - Colourants and inks other than those visibly present in or printed on housing or other components.
  - Phthalates of concern not mentioned above.
  - Dimethyl fumarate
  - Dinitrobenzenes
  - Dioxins and cogeners including polychlorinated and polybrominated dioxins and dibenzodioxins (PCDD and PBDD)
  - Furans and cogeners including polychlorinated and polybrominated furans and dibenzofurans (PCDF and PBDF)
  - Flame retardants (halogenated and non-halogenated)

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- Substances derived from Genetically Modified Organisms
- Hazardous Air Pollutants
- Heavy metals and their compounds
- Hydrazine
- Iso and di-isocyanates
- Jatropha derived substances
- MCCPs
- Metals in ink
- Microplastics (any type of plastic fragment used as a raw material that is less than 5 mm in length)
- Natural rubber latex or latex derivatives in the product or packaging
- Ozone depleting substances.
- PBT and vPvB substances
- Pharmaceutical components known to be at risk for melamine contamination.
- Polycyclic aromatic hydrocarbons
- Polystyrene (all types) in product or packaging
- PVC in packaging
- Radioactive substances
- Recycled materials, post-consumer or other source
- SCCPs
- Sensitizers such as rosin, colophony, R42 and R43
- Silicone containing oils, release agents or sprays.
- Styrene
- Substances derived from micro-organisms (not GMO)
- Thiurams
- Toluene

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

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.

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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

Hazardous thermal decomposition products:

CO, CO_2, Acrid Smoke, olefinic and paraffinic hydrocarbons, aldehydes, organic acids, ketones, alcohols, hydrogen cyanide, cyclic low molecular weight oligomers, acrolein, oxygenated hydrocarbons.

Warning: thermal decomposition of PTFE can also produce fume particles and various toxic gases including hydrofluoric acid and carbonyl fluoride.
Polymer fume fever – chills, nausea, shortness of breath, chest tightness, muscle or joint ache – seek immediate medical attention.

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, due to PTFE thermal decomposition risks.

SECTION 6 - Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

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

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

6.2 Environmental precautions

For unused product, 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 product, 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 used product and place in a designated, labelled waste container.

Care should be taken to consider the nature of any contamination on the product as the result of use and suitable PPE employed for handling medical waste. **See section 13 for disposal requirements.**

SECTION 7 – Handling and Storage

7.1 Handling

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

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/membrane.

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/membrane and maintain cleanliness of the unused product.

7.2 Storage

The article is supplied dry, without the presence of any preserving fluid. Store in clean, dry conditions suitable for a medical device.
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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.

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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 product 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 product remains clean during installation.
Environmental Exposure Controls:	Not normally required for the product itself as supplied.

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

SECTION 9 - Physical and Chemical Properties

Appearance:	Disposable filter
Physical state:	Solid
Colour:	Various
Solubility:	All components insoluble in water.
Auto-ignition temperature:	ABS/PP/EVA/acrylic: Typically > 300°C All other listed materials: Typically > 400°C.
Sensitive to shock:	Mechanical / thermal shock can result in damage.

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SECTION 10 – Stability and Reactivity

Reactivity:	The product is stable under the recommended conditions of use and storage.
Chemical Stability:	The product 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 product or its materials of construction. Do not allow fluids to freeze on the product.
	Incompatible Materials: Strong Acids, alkalis and oxidising Agents (e.g. Perchloric Acid, nitric acid), 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 product as supplied. Consult SDS of the product being filtered for specific advice and recommendations.

11.1 Acute Toxicity

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

11.2 Chronic health effects

No known significant effects or critical hazards of 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 products 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:

Warning: Do NOT incinerate unused filters with general waste, as combustion products of PTFE can be released and be hazardous to humans and the environment.

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.

Unused as supplied product: Disposal should be in-line with national legislation and local regulatory requirements for the materials present. As stated in sections 2 and 3.1, unused filters contain bonded glass fibres which may be released if disposal of unused product occurs without being treated as clinical waste.

Used product should be disposed of as clinical waste due to the nature of the contaminants as a result of use. Therefore, used products may be classified as hazardous – clinical waste.
Dispose of waste via a licensed waste disposal contractor.

Packaging

Bagging:	Plastic (Polyethylene/Polyester) / Polyethylene for bulk packed codes
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 product, supplied in its original packaging, is not classified as dangerous goods under ADR, RID, IMDG or IATA regulations.

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SECTION 15 – Change History

Rev number	Description of change
2	Converted to new Pall Medical template and included other variants in Appendix 1
AC	Section 3 revised concerning PFAS
AD	Added Vinyl Acetate to the California Proposition-65 list following the January 2025 update
AE	Added clarification on ADM
AF	Section 3 State of California section table revised to remove reference to DEHP in the PVC tubing due to a material upgrade. Information concerning phthalates in the polypropylene luer hub converted into a Note on page 6.
AG	6 new rows added to the table related to an existing component. The statement on PFAS in the PTFE revised due to a material sourcing change.

Notice to Reader

To the best of our knowledge, the information contained herein is accurate. However, Pall Medical assumes no 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

LSF1

LSF2

FORS2-BULK

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