Pall Corporation

PRODUCT SAFETY DATA INFORMATION

Date: 10 August 2021

Data Sheet Number: PSDI_IV and Acrocap family Revision: 5

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Pall Medical 0.2, 0.45, 0.8, 1.2 and 5.0 micron rated, disposable filter cartridges, each employing a Supor® hydrophilic polyether sulfone filter medium within an acrylic body and fitted with a vent PTFE membrane with a polyester support layer.

Example Product name(s): IV-2, IV-3, IV-5, IV-6, Micro IV, AEF, Acrocap®

Example Part Number(s): See appendix 1

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

- Aqueous IV solutions
- TPN and lipid solutions
- Drug therapy
- Apheresis solutions
- Any process requiring the removal of entrapped air from liquid solutions

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.

SECTION 3 - Materials of Construction

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

Material Name	CAS Number
Polyether sulfone (PES) membrane with hydrophilic surface modification	Pall proprietary information
Modified acrylic copolymer housing body	Polymer supplier proprietary information
Polytetrafluoroethylene (PFTE) membrane	9002-84-0
Polyester non-woven support layer	25038-59-9

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 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.

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

PFOA, its salts and PFOA related compounds are not intentionally used by Pall in the manufacturing processes of the above articles. 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 and Pall's knowledge of the processes it employs in production, levels of PFOA and PFOA related compounds are not known to exceed the following:

- 25 ppb PFOA
- 1000ppb PFOA-related compounds

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

Warning: Combustion products of PTFE (fluoropolymers) can be released and be hazardous to humans and the environment.
Hazardous thermal decomposition products: CO, CO_2, acrid smoke, SO_x, Benzenesulfonic acid, 2(or 4) methyl- phenol, ketones, aldehydes, hydrogen chloride, benzene, unsaturated hydrocarbons, hydrogen cyanide, organic acids, formaldehyde, nitrogen oxides, isocyanates, isocyanic acid, amines, isoprene, di-pentene

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.

Irritation to eyes. - suitable PPE and breathing apparatus precautions should be taken related to this risk in the event of fire.

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

Warning: Do NOT incinerate without additional consideration of risk emissions and residues resulting from combustion of PTFE

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:	Clear / blue / green / purple / red 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) PES components: 580°- 600°C, thermal decomposition >400°C PTFE components: 520° - 560°C, thermal decomposition >300°C Polyester components > 175°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 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.

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:

Material Name	Result	Species	Dose	Exposure
PES	LD50	Rat	>4000 mg/kg	oral
PTFE	LD50	Rabbit	7.88 g/kg	dermal

Irritation/Corrosion/Sensitisation: No known concern to unused filter as supplied

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. Unused filter cartridges may be used as land-fill.

Warning: Do NOT incinerate unused filters with general waste, as combustion products of PTFE (fluoropolymers) 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.

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.

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
6004423	AcroCap	CARDIOPLEGIA FILTERS
6014423	AcroCap	CARDIOPLEGIA FILTER - DBL VENT
6074421	IV-Infant	INFANT IV W/SUPOR 200; GENERIC
6074422	IV-AEF	GARDIAN 2 AEF NEONATE DLL
6074423	IV-AEF	Infant IV 0.2um Supor PTFE/RST NS Generic
6094421	IV-Infant	INFANT IV W/SUPOR 450; GENERIC
6104421	IV-Infant	NEONATE IV, SUPOR 1200 GENERIC
6104423	IV-AEF	G2 AEF NEONATE 1.2 SU W/HUB
6114423	IV-AEF	INFANT IV W/0.2UM SUPOR
6144423	AcroCap	HYDROPHOBIC AIR FLTR 0.45UM
6214423	IV-AEF	PEDIATRIC IV W/ 5UM SUPOR
6304420	IV-3	IV-3 W/SUPOR 200 HYDO STRIP
6344423	IV-AEF	INFANT IV W/0.2 +SUPOR
6444423	IV-AEF	INFANT IV W/0.2 +SUPOR
6464420	IV-2	I.V.-2 W/GREEN INLET; GENERIC
6484420	IV-3	IV-3 W/HP-200 GENERIC
6494420	IV-3	IV-3 Supor 0,2 um NS clear
6494521	IV-3	IV-3 CLR/GRN W/0.2UM N-200
6534420	IV-3	I.V.-3
6544420	IV-3	I.V.-3 FILTER
6544422	IV-AEF	GARDIAN 2 AEF
6564420	IV-3	I.V.-3 W/SUPOR 1200
6574422	IV-AEF	PEDIATRIC IV FILTER
6734520	IV-3	IV-3 filter 1.2UM Supor Membrane
6754520	IV-3	IV-3 filter 5.0 UM Supor Membrane
6814422	IV-AEF	GARDIAN 2 AEF, 0.2 um Supor
6944420	IV-3	G3 1.2 SUPOR
6954420	IV-3	G3 0.2+ SUPOR
6964420	IV-3	G3 0.2UM SUPOR
6994420	IV-3	GARDIAN 3 1.2UM
7024400	IV-5	GARDIAN 5 AEF 0.2 STD
7024402	IV-5	GARDIAN 5 AEF 0.2 STD
7024403	IV-5	IV-5, 0.2UM

7024409	IV-5	IV5 W/ 0.2 +SUPOR
7024410	IV-5	IV-5 W/0.2 SUPOR
7024411	IV-5	IV-5 W/1.2 SUPOR
7024412	IV-5	IV-5 1.2UM; CLEAR/ BLUE
7024413	IV-5	IV-5 W/5UM SUPOR, PURPLE
7034400	IV-5	IV-5 AEF .2 (+) STD.CONN
7043301	IV-5	IV-5 AEF W/ 0.8 SUPOR
7044400	IV-5	GARDIAN 5 AEF 1.2 STD
7044401	IV-5	IV-5 1.2UM
7224402	IV-6	Gardian 6 AEF 0.2um Generic
7224407	IV-5	IV5 /+0.2UM SUPOR
10012217	IV-5	IV5 W/0.2UM SUPOR
10012218	IV-5	IV5 W/1.2 UM SUPOR
69024421	IV-Micro	MCRO IV FLTR,SUPOR MEMB 2.3MM
69124421	IV-Micro	MICRO IV W/1.2 SUPOR - GENERIC
69144421	IV-Micro	MIV 0.2(+) 3/32 CLR
69154421	IV-Micro	MIV 0.2(+) 2MM CLR/RED GENERIC
69224421	IV-Micro	MICRO IV W/0.2 UM W/2MM I.D.
69244421	IV-Micro	MICRO IV 0.2 SUPOR
69254421	IV-Micro	MICRO IV 0.2 SUPOR 2.5 CNNCTR
69274421	IV-Micro	MIV 0.2(+) 2MM CLR/RED GENERIC
69314421	IV-Micro	MICRO IV W/0.2 UM W/2MM I.D.
69324421	IV-Micro	MICRO IV 0.2 SUPOR W/2.7MM ID
69384421	IV-Micro	G1 AEF 1.2UM 2.7 MM SOCKET
69404421	IV-Micro	G1 0.2UM W/1.98MM
69424421	IV-Micro	MICRO IV 1.2 UM 2 MM ID BLUE
69434421	IV-Micro	G1 .2(+)UM W/1.98MM
69444421	IV-Micro	MICRO IV W/5UM SUPOR
69454421	IV-Micro	MICRO IV 0.2 UM 3/32 I.D. GNRC
69464421	IV-Micro	MICRO IV W/5 SUPOR 2.3 CNNCTR
69474421	IV-Micro	MICRO IV W/0.2UM SUPOR 2.7MM
69494421	IV-Micro	GARDIAN 1, 1.2 UM, 3/32" BLUE
69554421	IV-Micro	MICRO IV 1.2 UM 2 MM ID BLUE
69724421	IV-Micro	MICRO IV W/+0.2UM SUPOR, 2.5MM
69814421	IV-Micro	MIV 0.2(+) 2MM CLR/CLR Generic
6074423J	IV-AEF	GARDIAN 2 AEF, FLL/MSL, CLEAR,
69744421E	IV-Micro	EURO MICRO IV POSIDYNE, 2MM