Pall Corporation

PRODUCT SAFETY DATA INFORMATION

Date:01.11.2019

Data Sheet Number: PSDS2019/HBG/rev2

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Sterile WBC Acrodisc® - Whole blood filtration device for the separation of white blood cells. The product comprises a polyester filter media (of polybutylene terephthalate membrane with a polyester non-woven support) in a polypropylene syringe filter housing. The outlet being white colour and inlet being natural polypropylene.

Example Product name(s): Sterile WBC Acrodisc

Example Part Number(s): AP-4951, AP-4952

The filters detailed above are NOT intended for patient protection in any applications.

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: None

Hazard statements: None

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	Percentage Composition
Polypropylene	9003-07-0	89 %
C.I Pigment White 6 3% (bonded) *	13463-67-7	1 %
Poly (butylene terephthalate)	30965-26-5	4 %
Polyester	25038-59-9	5 %
Hydrophilic Proprietary Surface treatment	/	<1 %
t-Butyl Alcohol	75-65-0	Trace

*The calcium carbonate and titanium dioxide are present in a colourant added to the Polypropylene of the outlet side of the syringe filter housing is fully bound which means the risks related to particulate release. The colourant is present in a 3% concentration with the Polypropylene resin in this one component. The hazardous materials of this colourant are encapsulated within the polypropylene resin; therefore, the materials are not GHS classified for health and environmental hazards as release and exposure is not expected.

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

Trace additives will not 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 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. Irritation may occur if large quantities of devices are being used and/or damaged. Flush eyes with water for 15 minutes and seek medical attention if irritation occurs.

Inhalation:	Inhalation is not considered a likely route of exposure for the filter product as supplied by Pall. Fibres from the filter media are unlikely to shed in quantities high enough to cause harm. If large quantities of devices are being used and/or damaged, this may result in the release of fibres, and pre-existing respiratory conditions may be aggravated; mild irritation to the respiratory tract. Remove individual to fresh air. If irritation persists, seek medical attention.
Skin Contact:	Fibres from the filter media are unlikely to shed in quantities high enough to cause harm. If large quantities of the devices are being used and/or damaged, released fibres larger than 5µm in diameter may cause mild irritation. Wash with soap and water. If irritation persists, get medical attention. The plastic is unlikely to cause irritation to skin. If irritation occurs, wash with soap and water. If irritation persists, seek 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. If ingested this may cause temporary, mild irritation. Rinse mouth. If irritation persists for more than 24 hours, 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, CO_2, water spray.

5.2 Specific Hazards

Warning: Combustion of polypropylene and the P White (3% colourant) may result in release of hazardous decomposition products such as: carbon monoxide, carbon dioxide and unburned hydrocarbons (smoke), Metal oxides, acids, Ketones, Alcohols, Aldehydes.

The formation of hydrocarbons and aldehydes are possible in the initial stages of fire (especially between 400 and 700 °C)

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.

Combustible particulate solid, will decompose under fire conditions.

Fight fire from safe distance with hose lines and monitor nozzles. Heat from fire may melt, decompose polymer and generate flammable vapours. Move containers from fire area if it can be done without risk. Evacuate immediately in the event of opening of storage container pressure relief devices of discolouration of container.

Do not allow run off from fire-fighting to enter drains or water courses. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Always stay away from tanks engulfed in fire. Do not attempt to get on top of storage containers involved in fire. Cool storage containers with large volumes of water even after fire is out.

SECTION 6 - Accidental Release Measures

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

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.

Due to the primary application of the device being blood filtration it is recommended that users wear gloves to reduce the risk of contamination.

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 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 cartridge 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.
Handle with care to avoid damage or abrading.

Store at temperatures between 4°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 – although the white colourant contains ingredients with exposure limits, the ingredients are bound within the polypropylene resin and therefore, release is not expected.

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

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

SECTION 9 - Physical and Chemical Properties

Appearance:	Disposable centrifugal spin device
Physical state:	Solid
Colour:	Hardware: Clear & White.
	Filter: White
Solubility:	Insoluble in water
Auto-ignition temperature:	> 175°C (Polyester components)
	>320 °C (Polypropylene components only)
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:	May be softened by some hydrocarbons and 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

None

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

Mutagenicity/ Carcinogenicity/ Reproductive Toxicity/ Teratogenicity: No known concern to unused filter as supplied (new & 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 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 devices: 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

Blister Packaging: Plastic moulding with a lid (Tyvek).

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

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

Part Numbers for which this sheet is applicable: AP-4951 & AP-4952.