

PRODUCT SAFETY DATA INFORMATION

Date: 31 July 2017

Data Sheet Number: PSDS2013/1/a Revision: 2

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Pall® disposable filter cartridges, employing a polypropylene construction (filter medium, supporting materials, and hardware) fitted with either a silicone elastomer, or ethylene propylene rubber O-ring seal option.

Example Product name(s): **Nexis® A, Nexis® T, Profile® II, Profile® Star, Profile® UP, HDC® II and Claris® products.**

Example Part Number(s): See Appendix 1.

The filters detailed above are intended for filtration and separation applications with compatible fluids – which do not soften, swell or adversely affect the filter, or its materials of construction. For use in line with Pall's instructions for use and within published recommended use conditions.

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	Weight %
Polypropylene	9003-07-0	96 – 100%
Silicone elastomer or Ethylene Propylene Rubber O-Ring Seal		<2%
Stainless-steel reinforcing ring*		<2%

*Stainless-steel reinforcing ring supplied with specific adaptor styles: AB code 7, 8, 3 and 2

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

Trace additives will be present in the plastic components- for example polypropylene antioxidants are present for stabilisation purposes.

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 (including Bisphenol-A) 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 polypropylene material employed in excess of the limits laid down.

Products in 'P' and 'W' options do not contain materials of direct animal origin (i.e. animal parts, tissues, or body fluids). However polypropylenes are known to contain trace levels of additives (e.g. calcium stearate) which are derived from tallow. Please be advised that 'P' and 'W' grade products employ polypropylene materials in line with the CPMP's *Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathies via human and veterinary medicinal products* (EMA410/01 rev 3) which gives specific consideration to bovine tallow derivatives and states 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 consult the SDS details for the product being filtered, for specific in process advice and how to 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.

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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 and consult the SDS of the product being filtered for specific advice.

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

5.2 Specific Hazards

Consult the SDS details of product being filtered for specific advice.

For the filter alone: No specific fire or explosion hazard. Hazardous thermal decomposition products: CO, CO₂, Acrid Smoke,

5.3 Advice to Fire Fighters

No special precaution required related to the filter alone. 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.

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, consult the SDS details of the product being filtered for specific advice on spillage, 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. Dispose of via a licensed waste disposal contractor.

Care should be taken to consider the nature of any contamination on the filter as the result of use and suitable PPE employed.

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 industrial hygiene practice. Eating, drinking and smoking are prohibited in areas where this product is handled, stored or processed. Workers 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 and o-ring seals. 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 the process fluids used and potential contaminant. 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 0°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.

7.3 Shelf life

Pall recommends a customer shelf life of 5 years, from the date of manufacture, provided the product has been stored in accordance with the conditions laid out in section 7.2.

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 industry 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: Filter Cartridge with elastomeric seals options.

Physical state: Solid

Colour: White filter, with optional silicone (tan /brick red) or EPR (black) colored elastomeric seals.

Melting Point: Typically 130°C – 170°C (for polypropylene)
>200°C (for elastomeric seals)

Flash Point: Polypropylene typically > 315°C

Solubility: Insoluble in water.

Auto-ignition temperature: Polypropylene typically >301°C

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Sensitive to shock: Mechanical / thermal shock can result if 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.

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. Consult Pall if the filter is to be used for continuous periods at 82°C or more.

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

Product/Ingredient Name	Result	Species	Dose	Exposure
Polypropylene	LD50 Oral	Rat	>8g/kg	-

Irritation/Corrosion/Sensitisation: No known concern

Mutagenicity / Carcinogenicity / Reproductive Toxicity / Teratogenicity: No known concern

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.

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11.2 Chronic health effects

No known significant effects or critical hazards for the unused filter as supplied.

Carcinogenicity: Classified 3 (Not classifiable for humans.) by IARC [Polypropylene].

SECTION 12 - Ecological Information

Polypropylene 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: Disposal/handling of the used and 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 or incinerated via an approved process. Due consideration shall be made to the nature of the contaminants on the filters as a result of use.

Hazardous Waste: To the best of our knowledge, this product if un-used is not regarded as hazardous waste as defined by the EU Directive 91/689/EEC and amendments. Due consideration must be made to the nature of the contaminants on the filters as a result of use, when considering whether the used filters are classified as hazardous 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.

SECTION 15 - Regulatory Information

See section 3

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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.

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APPENDIX 1 –**Example part numbers including filters fitted with silicone elastomer or ethylene propylene rubber (EPR) seals.****Product: Nexis A Filters**

Part Number: NXA _ _ _ * U % {} ^

where (*) indicates nominal filter length
(_ _ _) indicates media grade
(%) indicates cartridge code style
(^) indicates the gasket seal code: "S"- silicone elastomer, "E" - EPR

Country of origin: Made in the USA

Product: Nexis T Filters

Part Number: NXT _ _ _ * U % {} ^

where (*) indicates nominal filter length
(_ _ _) indicates media grade
(%) indicates cartridge code style
(^) indicates the gasket seal code: "S"- silicone elastomer, "E" - EPR
({}) indicates the market option: 'W480' – food and beverage

Country of origin: Made in the USA

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Product: **Profile II Polypropylene Filters**

Part Number: R*F _ _ _ {}

where (*) indicates nominal filter length
(_ _ _) indicates media grade
({}) indicates the market option: 'W' – food and beverage

Part Number: AB *Y _ _ _ % {} ^

where (*) indicates nominal filter length
(_ _ _) indicates media grade
(%) indicates cartridge code style
(^) indicates the o-ring seal code: "H4"- silicone elastomer, "J" - EPR
({}) indicates the market option: 'W' – food and beverage. 'P' - Biotech

Country of origin: Made in Puerto Rico, USA, or UK

Product: **Profile Star Filters**

Part Number: AB *A _ _ _ % {} ^

where (*) indicates nominal filter length
(_ _ _) indicates media grade
(%) indicates cartridge code style
(^) indicates the o-ring seal code: "H4"- silicone elastomer, "J" - EPR
({}) indicates the market option: 'W' -food and beverage. 'P' - Biotech

Part Number: AB *TF% {} ^

Where (*) indicates nominal filter length
(%) indicates cartridge code style
(^) indicates the o-ring seal code: "H4"- silicone elastomer, "J" EPR
({}) indicates the market option: 'W' – food and beverage

Country of origin: Made in the UK

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Product: Profile UP Filters

Part Number: AB*UY___% ^

where (*) indicates nominal filter length
(__) indicates media grade
(%) indicates cartridge code style
(^) indicates the gasket seal code: "H4" - silicone elastomer, "J" – EPR

Part Number: PUY*UY__ _J

Where (*) indicates nominal filter length
(__) indicates media grade
"J" indicates the gasket seal code for EPR

Country of origin: Made in the USA

Product: HDC II Filters

Part Number: AB *J__ _ % ^

where (*) indicates nominal filter length
(__) indicates media grade
(%) indicates cartridge code style
(^) indicates the o-ring seal code:
"H4" - silicone elastomer, "J" - ethylene propylene rubber.

Country of origin: Made in Puerto Rico, USA, or UK

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Product: Claris Filters

Part Number: CLR _ _ _ * % {} ^

where (*) indicates nominal filter length

(_ _ _) indicates media grade

(%) indicates cartridge code style

(^) indicates the gasket seal code: "S" - silicone elastomer, "E" - EPR

({}) indicates the market option: 'W' – food and beverage

Country of origin: Made in the USA