

PRODUCT SAFETY DATA INFORMATION

Date: December 11th, 2023
Data Sheet Number: GPS-00241 rev1.0

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Food Contact Compliant Seitz® Filter Sheets

Example Product name(s): Seitz D400 and PERMAdur® S Support Sheets

Seitz AKS4, AKS FB, BS, FA, G, HR, HS, IR, K, T and ZD Series Filter Sheets

The sheet filters detailed above are not intended for patient protection 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: Not Applicable

Hazard statements: Not Applicable

Special packaging requirements: Not Applicable

SECTION 3 - Materials of Construction

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

Material Name	Sheet Grades	CAS Number	Percentage Composition
Activated Carbon*	AKS4, AKS FB	7440-44-0	40 - 60
Cellulose*	D400, PERMAdur S, AKS4, AKS FB, BS, FA, G, HR, HS, IR, K, T	65996-61-4	20 to 100
	ZD only	9004-34-6	
Diatomaceous Earth* Kieselguhr, Natural	AKS4^, BS, FA, G, HR, HS, IR, K, T	61790-53-2	<1 to 65
Perlite*	AKS4^, BS, FA, G, HR, HS, IR, K, T	93763-70-3 / 130885-09-5	<1 to 50
Polyolefin fibers*	BS, HR	9002-88-4 / 9002-89-5	<1 to 40
	^AKS4, G, K, HS, IR, K, T		
	PERMAdur S only	25038-59-9 & 26221-73-8	

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Pall Proprietary Epichlorohydrin Resin Bonding Materials	All	Pall Proprietary Information	<1 to 10
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* Chemically bonded to preclude release of dust or fibres from other components.

^ indicates the substances is present as a trace material

by in process recycling.

These products are 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 for sheet-based module products, 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.

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Eye Contact:	Unlikely route of exposure if used under recommended conditions. Wash with water, continuing for 10 minutes. Remove contact lenses and raise eyelid first. Seek medical attention if adverse symptoms are experienced.
Inhalation:	Unlikely route of exposure if used under recommended conditions. If dust is inhaled and adverse symptoms experienced, seek medical attention.
Skin Contact:	Unlikely route of exposure if used under recommended conditions. If experiencing irritation, wash with soap and water. Seek medical attention if irritation or other symptoms are experienced.
Ingestion:	Unlikely route of exposure if used under recommended conditions. Rinse mouth with water and give plenty of water to drink. Do not induce vomiting unless instructed to do so by medical personnel.
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.

5.2 Specific Hazards

Not applicable.

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

Avoid dust formation and avoid breathing dust.

For used filter sheets always address any contaminants present on the sheets as the result of use.

6.2 Environmental precautions

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For unused filter sheets, 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 sheets, 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 sheet 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 sheets and maintain cleanliness. Handling of used filter sheets 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 0°C and 45°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.

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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

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 sheets remain clean during installation.

Environmental Exposure Controls: Not normally required for the filter sheets as supplied.

After the filter sheet 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: Solid, Black (AKS only) or Beige/Cream

Physical state: Solid

Colour: Black or Beige/Cream

Solubility: Not Applicable

Auto-ignition temperature: > 200 °C (392 °F)

Activated Carbon: 300-375 °C (572 – 707 °F)

Cellulose: 254 °C (489 °F)

Diatomaceous Earth Kieselguhr, Natural: Not applicable (mineral product)

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Perlite: Not applicable (mineral product)

Polyolefin fibres: 330-410 °C (626 -770 °F)

Resin: Not applicable

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:	Reactive or incompatible with the following materials: oxidizing materials and 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 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 Sheet filters:

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.

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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

SECTION 12 - Ecological Information

Unused Pall filter sheets are 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 Pall depth sheet filters as supplied originally may be disposed of or composted with normal house garbage in accordance with official local regulations. This does not refer to the depth filter sheet after its use. Here, the influence of the filtered product must be taken into consideration. The waste code No. is to be individually fixed with the local waste disposal company.

Note that AKS sheets contain activated carbon. These sheet grades may require different local disposal considerations.

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.

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 landfill should only be considered where recycling is not feasible.

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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.

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