

DECLARATION OF COMPLIANCE Oenopure™ Filter Cartridges AB Style “W” Code

Cartridge Part Number

AB W
Table 1 Table 2 Table 3 Table 4

This is a guide to the Part Numbering structure only. For specific options, please contact Pall.

Table 1 : Nominal Length

Code	Description
1	254 mm (10")
2	508 mm (20")
3	762 mm (30")
4	1016 mm (40")

Table 2 : Microbial Removal Rating

Code	Description
GB	0.45 µm
GK	0.65 µm

Table 3 : Adaptor

Code	Description
3	SOE – single open end with flat closed end and external 222 O-rings
7	SOE – single open end with fin end, 2 locking tabs and external 226 O-rings
8	SOE – single open end with fin end and external 222 O-rings
28	SOE – single open end with fin end, 3 locking tabs and external 222 O-rings

Table 4 : O-ring Seal Material

Code	Description
H4	Silicone Elastomer
J	Ethylene Propylene Rubber

The Oenopure filter cartridge uses single layer Supor® filter membrane in a polypropylene filter construction.

Oenopure filters are suitable for use in microbial removal from aqueous-based food and beverage products.

An initial flush is recommended prior to use.

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 Reference FBDCOENOP1ENj
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Oenopure Filter Cartridges (“W” Code)

Components

Filter Membrane	Supor hydrophilic polyethersulfone membrane
Support / Drainage	Polypropylene
Cage	Polypropylene with titanium dioxide filler
Core, End Cap and Fin End	Polypropylene
Adaptor	Polypropylene with a stainless steel reinforcing ring as appropriate to design
O-ring Seal	Ethylene Propylene Rubber (J) or Silicone Elastomer (H4)

Declaration

Oenopure AB style “W” Code filter cartridges comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

Europe

The “W” Code Oenopure filter cartridges meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

- Our suppliers information indicates that the polymeric materials used to produce “W” Code Oenopure filter cartridges are made from monomers and additives consistent with Annex I of Commission Regulation (EU) Number 10/2011 and its amendments, relating to plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

Migration testing of Oenopure GBW materials of construction have been performed, and met migration criteria after flushing and in flow conditions, in:

Simulant A (10% ethanol), 4 hours at reflux

Simulant B (3% acetic acid), 4 hours at reflux

and distilled water, 4 hours at reflux.

Minimum flow rate required: 0.2 kg/hr per 10” filter module.

Note:

This product contains materials that are subject to Specific Migration Limit (SML) requirements.

This product contains calcium stearate, which is approved as a direct food additive.

USA

The materials of construction meet the FDA requirements for food contact use as detailed in Code of Federal Regulations, 21 CFR paragraphs 170-199 in that:

- Polypropylene to 21 CFR section 177.1520 (Olefin polymers)
- Polyethersulfone resin to 21 CFR section 177.2440 (Polyethersulfone resins)
- Ethylene Propylene Rubber and Silicone Elastomeric seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils)

Process Quality System

Site of Manufacture: Pall Cortland, USA and Pall Manufacturing (UK) Ilfracombe, UK on behalf of Pall International Sàrl.

The Quality Management System at Pall Cortland and Pall Manufacturing (UK) Ltd., Ilfracombe, are certified to ISO 9001:2008. These products / product packaging carry a lot number / date code to facilitate traceability to suppliers’ materials and Pall production records.

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