PALL CORPORATION

DECLARATION OF COMPLIANCE
Oenopure™ II Filter Cartridges
AB Style "W" Code

Cartridge Part Number

AB [ ] LK [ ] W [ ]
Table 1 Table 2 Table 3

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 : 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 3 : O-ring Seal Material

Code	Description
H4	Silicone Elastomer
J	Ethylene Propylene Rubber

The Oenopure II filter cartridges use a single layer of Supor® LK (0.65 µm) filter membrane in a polypropylene filter construction.

Oenopure II filters are suitable for microbial removal from aqueous-based, low alcohol, food and beverage products, such as wine.

An initial flush is recommended prior use.

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Reference	FBDCOENOP2ENk
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Oenopure II Filter Cartridges ("W" Code)

Components

Filter Membrane	One layer of hydrophilic Supor 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
O-ring Seal	Ethylene Propylene Rubber (J) or Silicone Elastomer (H4)

Declaration

Oenopure II "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 II 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 II 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 II LBW materials has 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
  and met migration limits at a minimum flow of 0.2 kg/hr for a 10" 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.

Users should satisfy themselves that these materials are suitable for use in their specific food application.

USA

The raw 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)
- Samples of Supor membranes were analyzed as per ASTM test method for conformance to FDA specifications for food contact substance. The membrane met the specifications of polyethersulfone resins as detailed in Title 21 of the US Code of Federal Regulations 177.2440 paragraphs (a), (b) and (c) include acceptable heavy metal content. Additionally no specified or known adjuvants were detected at a limit of 0.001 %.

Note: this product may contain trace levels of titanium dioxide, a chemical known to the state of California to cause cancer. The listing for titanium dioxide is for “airborne, unbound particles or respirable size.” The listing is not applicable to titanium dioxide within a product matrix such as polypropylene.

Process Quality System

Site of Manufacture: Pall Cortland, USA

The Quality Management System at Pall Cortland is certified to ISO 9001:2015.

These products / product packaging carry a lot number / date code to facilitate traceability to suppliers’ materials and Pall production records.

Pall Cortland confirms that the product is manufactured in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

Supplied in Europe by

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