



# Food and Beverage

## DECLARATION OF COMPLIANCE Oenopure™ II Filter Cartridges

AB Style "W" Code

Part Number: AB    W   
Table 1 Table 2 Table 3 Table 4

This is a guide to the part number structure only, for availability of specific options, please contact Pall.

**Table 1: 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 |
|------|-------------|
| LB   | 0.45 µm     |
| LK   | 0.65 µm     |

**Table 3: Adapter**

| 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** II filters each use a single layer of Supor® LB (0.45 µm) or LK (0.65 µm) filter membrane in a polypropylene filter construction. **Oenopure** II filters are suitable for microbial removal from aqueous-based, slightly alcoholic food and beverage products, such as wine.

**Issued:** 1 May 2009  
**Expiry:** 30 April 2010  
**Reference:** FBDCOENOP2EN  
**Page:** 1 of 3

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Director of Regulatory Affairs  
Western Hemisphere

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European Quality Manager

## Oenopure II Filter Cartridges (AB Style "W" Code)

- **COMPONENTS**

|                      |                                                                         |
|----------------------|-------------------------------------------------------------------------|
| Filter Membrane:     | One layer of <b>Supor</b> hydrophilic, polyethersulfone filter membrane |
| Support/Drainage:    | Polypropylene                                                           |
| Cage:                | Polypropylene with titanium dioxide filler                              |
| Core:                | Polypropylene                                                           |
| End Cap and Fin End: | Polypropylene                                                           |
| Adapter:             | Polypropylene with internal stainless steel reinforcing ring            |
| O-ring Seal:         | Ethylene Propylene Rubber (J) or Silicone Elastomer (H4)                |

- **DECLARATION**

**Oenopure** II LBW and LKW filter cartridges comprise of materials that our suppliers state meet regulatory and legislative requirements and guidelines for food contact in that:

- **EEC**

The "W" Code **Oenopure** II filters meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

The polymeric materials used to produce "W" Code **Oenopure** II filters are made from monomers and additives listed in EU Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

Migration testing of the **Oenopure** II LBW materials has been performed in simulants A, B, and C after flushing and in flow conditions.

- **USA**

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

Polypropylene to section 21 CFR 177.1520 (Olefin polymers)

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)

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

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) including acceptable heavy metal content. Additionally, no specified or known adjuvants were detected at a limit of 0.001 %.

- **PROCESS QUALITY SYSTEMS**

**Site of Manufacture:** Pall Cortland, USA - a Division of Pall Corporation

The Quality Management System at Pall Cortland is certified to ISO 9001:2008.

- **SUPPLIED IN EUROPE BY:**

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