

# DECLARATION OF COMPLIANCE

## Oenoclear™ II Filter Cartridges

### AB Style “W” Code

### Cartridge Part Number

AB  Table 1
  
 ST  Table 2
  
 W  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
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 Oenoclear II filter has a filter medium layer (comprised of resin-bonded liquid crystal fibers on a cellulose substrate) and polyester non-woven support and drainage materials in a polypropylene hardware configuration.

This filter is intended for pre-filtering of wine.

An initial flush is recommended prior use.

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## Oenoclear II Filter Cartridges (AB Style “W” Code)

### Components

Filter Medium	Resin bonded liquid crystal fibers on a cellulose substrate
Support / Drainage	Polyester non-woven
Side Seal Clip	Polypropylene
Cage	Polypropylene with TiO <sub>2</sub> colorant
Core, End Cap and Fin End	Polypropylene
Adaptor design*	Polypropylene with internal stainless steel reinforcing ring as appropriate to design*
O-ring Seal	Ethylene Propylene Rubber (J) or Silicone Elastomer (H4)

\*For applications requiring autoclaving or steam sterilization, Pall recommends the use of Code 7 adaptors to ensure filter sealing after cooling. Cartridges should be cooled to system operating temperature prior to use.

### Declaration

Oenoclear 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 Oenoclear II filters meet the requirements for food contact, in that:

- The filter medium of this product is composed of two or more layers of material, one of which does not consist exclusively of plastics. The plastic components of this medium meet the requirements listed in Commission Regulation (EU) Number 10/2011 on plastic materials and articles intended to come into contact with foodstuffs.
- The cellulose substrate material complies with European Regulation (EC) Number 1935/2004.
- The polypropylene end caps, cage, core, adaptor and fin of this product - together with the polyester support/drainage layer - meet the requirements scoped in Commission Regulation (EU) Number 10/2011, and its amendments, on plastic materials and articles intended to come into contact with foodstuffs.

Overall migration testing of an AB1ST7WH4 filter was conducted, and met migration criteria after flushing and in flow conditions, in:

Simulant B (3% acetic acid) for 2 hours at 70 °C (158 °F)

Simulant C (20% ethanol), for 2 hours at 70 °C (158 °F)

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.

This product employs a BADGE resin.

- Samples of the silicone elastomeric (H4) and EPR (J) seal material formulations, typically used with the above part numbers, have been tested as 226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid and 20 % ethanol, under reflux conditions for 4 hours - repeat use. In respect of the overall migration limit for food contact elastomers according to the French requirements (given in Arrete of November 9th 1994 and published in Journal Officiel de la Republique Francaise, December 2nd 1994, p17029-17036) is 10 mg/dm<sup>2</sup>, data obtained with the rubber o-rings under the tested conditions was well within this limit.

The volatile levels from samples of the silicone elastomer (H4) formulation, after heating at 200 °C (392 °F) for 4 hours, was found to be within the BfR section XV specification for this material.

Our supplier states that the EPR (J) seal formulation is suitable for food contact use under BfR XXI category 4.

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

## USA

- The liquid crystal fibers have an FCN Number 174.

The following 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:

- Resin binder material to 21 CFR section 175.105 (Adhesives)
- Resin component to 21 CFR section 176.170 (Components of paper and paperboard in contact with aqueous and fatty foods)
- Cellulose substrate material to 21 CFR section 176.170 (Components of paper and paperboard in contact with aqueous and fatty foods)
- Polyester to 21 CFR section 177.1630 (Polyethylene phthalate polymers)
- Polypropylene to 21 CFR section 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)

## Process Quality System

Site of Manufacture: Pall Manufacturing (UK) Ltd., Ilfracombe, UK in behalf of Pall International Sàrl.

The Quality Management System at Pall Manufacturing (UK) Ltd., Ilfracombe, 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 Manufacturing (UK) Ltd., Ilfracombe, confirm that the product manufacturing environment, for the above product at our site, is in-line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

## Supplied in Europe by

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