

DECLARATION OF COMPLIANCE Pall® Oenofine XL Filter Modules

“W” Code

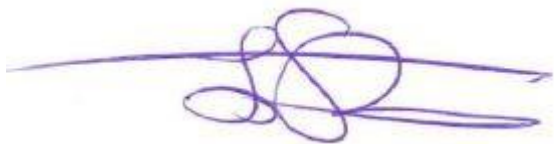
Module Part Numbers:

WUSP-6443

The Oenofine XL filter modules are designed for contact with non-fatty foodstuffs. These modules can be used with aqueous and alcoholic foodstuffs (up to 65 % alcohol) at up to 40 °C (104 °F) in filtration flow conditions, following flushing and in flow conditions.

An initial flush is mandatory prior to use.

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Reference	FBDCOFINEENi
Page	1 of 3



Lorenz Streng
Quality Manager
Pall Filtersystems GmbH

Oenofine XL Filter Modules (W Code)

Components

Membrane	PVDF
Housing	Polysulfone
Potting and Cross-plate	Epoxy Resin
Netting	Polyethylene
Sleeve	Polypropylene
O-ring Seal	Ethylene Propylene Copolymer

Note: may contain trace levels of Bisphenol A

The modules are packaged with the following solution:

Glycerin 65 %, Ethanol 2 % and Water 33 %

The modules must be flushed prior to use to remove this solution.

Declaration

Oenofine XL filter WUSP-6443 modules comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

Europe

The "W" Code Oenofine XL module, WUSP-6443, meets the requirements for food contact as detailed in European Regulation (EC) Numbers 1935/2004 in that:

- The products have been assessed by the manufacturer, in conjunction with a Consulting and Testing Service, under the Plastics Materials and Articles in Contact with Foodstuffs Regulations laid out in EU Regulation (EU) number 10/2011. All substances identified as being used in the manufacture of the above products were (a) listed in the above legislation either with or without restrictions, or (b) not subject to the provisions of the above legislation.
- The supplier certifies that the materials of construction are not subject to the provisions of EC Regulation 1895(2005) and/or do not use BADGE, BFDGE or NOGE.
- Tests have shown that the WUSP-6443 module will meet the Specific Migration Limits and the Overall Migration Limits in 3 % acetic acid and alcoholic liquids up to 65 % ethanol when tested under conditions of repeat usage at 40 °C (104 °F), provided that the flow rate through the filters is greater than the minimum recommended flow rate of 90 L per hour

USA

The manufacturer states that the following materials of construction are listed for food contact use as detailed in Code of Federal Regulations, 21 CFR paragraphs 170-186 in that:

- Polyethylene to 21 CFR section 177.1520 (Olefin polymers)
- PVDF to 21 CFR section 177.2510 (Polyvinylidene fluoride resins)
- Polysulfone to 21 CFR section 177.1655 (Polysulfone resins)
- Epoxy resin to 21 CFR section 175.300 (Resinous and polymeric coatings)
- Polypropylene to 21 CFR section 177.1520 (Olefin polymers)

Note: may contain trace levels of Bisphenol A - a chemical subject to State of California Prop-65 listing. BPA is known to cause reproductive toxicity.

Process Quality System

Country of Origin: Japan

This product is manufactured under a Quality Management System certified to ISO 9001:2008.

Contact in Europe

Pall Filtersystems GmbH
Planiger Strasse 137
55543 Bad Kreuznach
Germany

Supplied in Europe by

Pall International Sàrl
Av. De Tivoli
1700 Fribourg
Switzerland



Pall Corporation


Pall Food and Beverage

New York - USA
+1 516 484 3600 telephone
+1 866 905 7255 toll free
foodandbeverage@pall.com

Visit us on the web at www.pall.com

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