

DECLARATION OF COMPLIANCE
Pall® Oenofine XL Filter Modules
“W” Code

Module Part Numbers:

PWUSP-6443 for Oenofine PRO XL systems
PWUSP-6443H for Oenofine PRO XL HP systems

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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Pall Sàrl and MEA QARA Manager

Components

Membrane	PVDF
Housing	Polysulfone
Potting and Cross-plate	Epoxy Resin
Netting	Polyethylene
Sleeve	Polypropylene
O-ring Seal	Ethylene Propylene Copolymer
Housing Coating	FRP (for PWUSP-6443H only)

The modules are packaged with an aqueous glycerin solution: Glycerin 65 % and Water 35 %. The glycerin employed is stated by the supplier to be from a plant source and exempt from REACH registration under Annex V. The modules must be flushed prior to use to remove this solution.

Declaration

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

Europe

The “W” Code Oenofine XL module, PWUSP-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 above modules 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 for 10 days 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.

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

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:



WARNING:

This product can expose you to chemicals including BPA, DBP and DEHP which are known in the State of California to cause birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

Process Quality System

Manufactured in Japan and Supplied by Pall Sàrl. Made in Japan.

This product is manufactured under a Quality Management System certified to ISO 9001:2015.

Supplied in Europe by

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Pall Corporation has offices and plants throughout the world. To locate the Pall office or distributor nearest you, visit www.pall.com/contact.

The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

IF APPLICABLE Please contact Pall Corporation to verify that the product conforms to your national legislation and/or regional regulatory requirements for water and food contact use..

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