

**DECLARATION OF COMPLIANCE
Pall® Oenofine XL Filter Modules**

“W” Code

Module Part Numbers:

WUSP-6443 for Oenofine PRO XL systems

WUSP-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.

Issued	1 May 2010
Revision	1 April 2021
Expires	28 February 2023
Reference	FBDCOFINEENo
Page	1 of 3



Mario Basters
Quality Assurance & Regulatory Affairs 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
Housing Coating	FRP (for WUSP-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 WUSP-6443 and WUSP-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, 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 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 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

Country of Origin: Japan

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

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 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

Pall Corporation has offices throughout the world. For Pall representatives in your area, please go to www.pall.com/contact.

Because of developments related to products, systems and/or services described herein, the data and procedures are subject to change without notice. Please consult your Pall representative or visit www.pall.com to verify that this information remains valid.

© Copyright 2021, Pall Corporation. Pall and  are trademarks of Pall Corporation. ® indicates a trademark registered in the USA.