

DECLARATION OF COMPLIANCE Oenoflow™ HS Filter Modules

"W" Code

Module Part Numbers:

PWUMW-553

Oenoflow HS modules are composed of components considered suitable for use with non-fatty foods and beverages in flow conditions after flushing and in flow conditions.

An initial flush is mandatory prior to use.

Issued 1 December 2010 Revised 28 May 2024 Expires 28 February 2027 Reference FBDCOEHSENn

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Components

Membrane PVDF (polyvinylidine fluoride)

Housing Polysulfone
Potting and Cross-plate Epoxy Resin
Sleeve Polypropylene

O-ring Seal Ethylene Propylene Copolymer

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

Oenoflow HS filter modules comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

Europe

The "W" Code Oenoflow HS modules meet the requirements for food contact as detailed in European Regulation (EC) Number 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 PWUMW-553 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 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 materials of construction are listed in the FDA requirements for food contact use as detailed in Code of Federal Regulations, 21 CFR paragraphs 170-186 in that:

- 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)
- Ethylene Propylene Co-polymer seal to 21 CFR section 177.2600 (Rubber articles intended for repeated use excluding milk and edible oils)

Note:



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. Made in Japan.

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

Contact in Europe

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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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MAY 2024