

DECLARATION OF COMPLIANCE Oenoflow[™] HS Filter Modules

"W" Code

Module Part Numbers:

WUMW-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.

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Lorenz Strenge Quality Manager Pall Filtersystems GmbH

Oenoflow HS Filter Modules (W Code)

Components

Membrane	PVDF (polyvinylidine fluoride)
Housing	Polysulfone
Potting and Cross-plate	Epoxy Resin
Sleeve	Polypropylene
O-ring Seal	Ethylene Propylene Copolymer

Note: may contain trace levels of Bisphenol A The modules are packaged with the following solution: The modules must be flushed prior to use to remove this solution.

Glycerin 65 %, Ethanol 2 % and Water 33 %

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 WUMW-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 at 40 °C (104 °F), provided that the flow rate through the filters is greater than the minimum recommended flow rate of 9.7 L per hour.

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: 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

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Supplied in Europe by

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