

## 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.

An initial flush is recommended prior to use.

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## Oenofine XL Filter Modules (W Code)

### Components

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

Note:

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

- **Europe**

The "W" Code Oenofine XL modules meet the requirements for food contact as detailed in European Regulation (EC) Numbers 1935/2004 and 10/2011 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 10/2011 (which replaces EC Directive 2002/72/EC and its amendments, effective from 1 May 2011). All substances identified as being used in the manufacture of the above products are (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 module meets the Specific Migration Limits and the Overall Migration Limits into 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 indicated below.

WUSP-6443 – 90 liters 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:

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)

## Process Quality System

Country of Origin      Japan

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

## Supplied in Europe by

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