

## DECLARATION OF COMPLIANCE SUPRApak<sup>™</sup> Depth Filter Modules SW 7700 "W" Code

### **Module Part Number**



This is a guide to the Part Numbering structure only. For specific options, please contact Pall.

# Code Description 7700 SW Range M 250 mm (9.8") / 183 mm (7.2") L 250 mm (9.8") / 415 mm (16.3")

SUPRApak SW7700 filter modules incorporate a variety of proprietary depth filter media in a convenient, disposable filter module, with polypropylene hardware and polyester straps.

SUPRApak SW7700 filter modules may be used for non-alcoholic, alcoholic beverages and oils.

An initial flush is recommended prior to use.

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Lorenz Strenge Quality Manager Pall Filtersystems GmbH

#### SUPRApak Depth Filter Modules (SW7700 Range "W" Code)

#### Components

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Hardware	
Tubular center core	Polypropylene (20% talc filled)
Intermediate rings	Polypropylene (20% talc filled)
Attaching straps	Polyester
Filter Media	$\operatorname{Seitz}^{\scriptscriptstyle (\!$

#### **Declaration**

SUPRApak SW7700 depth filter modules comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

#### **Europe**

The "W" Code SUPRApak SW7700 depth filter modules meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

• The cellulose filter sheet material components comply with German Recommendation XXXVI and XXXVI/1 as well as with the German Foodstuffs and Animal Feed Code (LFGB §§30 and 31).

Sheet materials have been extraction tested with hot water at 85 °C (185 °F) to German Recommendation XXXVI/1.

Our suppliers state that the polypropylene (20% talc filled) and polyester used to make the hardware components are
produced in accordance with the lists in European Regulation (EC) Number 10/2011 and its amendments relating to
plastic materials and articles intended to come into contact with foodstuffs.

Migration testing of the polypropylene (20% talc filled) hardware components was also performed in the following simulants for use after flushing and in flow conditions: Simulant B (6% acetic acid) at 85 °C (185 °F) for 30 minutes Simulant D2 (Sunflower oil) at 88 °C (190 °F) for 30 minutes plus Distilled Water at 40 °C (104 °F) for 30 minutes, 80% ethanol at 60 °C (140 °F) for 150 minutes and Isooctane as an oil replacement at 60 °C (140 °F) for 30 minutes

A pigment in the polypropylene is to BfR Recommendation IX.

 Our supplier states that the polyester used to make the attaching straps is in accordance with Annex 1 of European Commission Regulation (EU) Number 10/2011.

Migration testing of the polyester hardware components was also performed in the following simulants for use after flushing and in flow conditions: Simulant B (6% acetic acid) at 85 °C (185 °F) for 30 minutes Simulant D2 (Olive oil) at 85 °C (190 °F) for 30 minutes plus Distilled Water at 40 °C (104 °F) for 30 minutes and 80% ethanol at 60 °C (140 °F) for 150 minutes

Note:

This product contains materials that are subject to Specific Migration Limit (SML) requirements.

This product contains calcium stearate, which is approved as a direct food additive.

#### USA

The following raw materials of construction meet the FDA requirements for food contact use as detailed in Code of Federal Regulations, 21 CFR paragraphs 170-199 for the filtration of bulk alcohol beverages not exceeding 80% alcohol by volume, at temperatures not exceeding 60 °C (140 °F).

- Polypropylene (employed hardware) to 21 CFR section 177.1520 (Olefin polymers) with Polypropylene pigment to 21 CFR section 178.3297 (Colorants for polymers)
- Polyester (employed in strap) to 21 CFR section 177.1630 (Polyethylene phthalate polymers)
- Cellulose and binder resin to 21 CFR section 177.2260 (Filters, resin bonded) and to 21 CFR section 176.170 (Components
  of paper and paperboard in contact with aqueous and fatty foods).
- Total filter sheet material extractables as per 21 CFR section 177.2260 (Filters, resin bonded) (g) (h) (i) (j) (k) (l) 50 % ethanol at room temperature and n-hexane at reflux were used in the extractables testing.

#### **Process Quality System**

Site of Manufacture: Pall Filtersystems GmbH, Bad Kreuznach, Germany on behalf of Pall International Sàrl.

The Quality Management System at Pall Filtersystems GmbH, Bad Kreuznach is certified to ISO 9001:2008

These products / product packaging carry a lot number / date code to facilitate traceability to suppliers' materials and Pall production records.

#### Supplied in Europe by

Pall International Sàrl Av. de Tivoli 3 Fribourg Switzerland CH-1700



#### 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

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