

## DECLARATION OF COMPLIANCE SUPRAPAK™ Depth Filter Modules SW 7700 “W” Code

### Module Part Number

SUPRAPAK SW   W  
Table 1   Table 2

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

**Table 1 : Product Grade**

Code	Description
7700	SW Range

**Table 2 : Nominal Dimensions**

Code	Description
S	250 mm (9.8") / 183 mm (7.2")
M	250 mm (9.8") / 285 mm (11.2")
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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Page	1 of 3



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 Quality Assurance & Regulatory Affairs Manager  
 Pall Filtersystems GmbH

## SUPRApak Depth Filter Modules (SW7700 Range “W” Code)

### Components

#### Hardware

Tubular center core Polypropylene (20% talc filled)

Intermediate rings Polypropylene (20% talc filled)

Attaching straps Polyester

**Filter Media** Seitz® depth filter sheet material consisting of cellulose and binder resin

### 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.

Users should satisfy themselves that these materials are suitable for used in their specific food application.

## 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 9001:2015.

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

Pall Filtersystems GmbH confirm that this product is manufactured in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

## Supplied in Europe by

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