

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

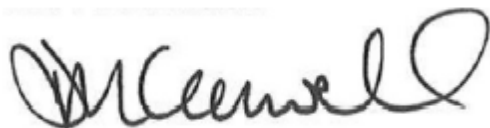
Code	Description
S	250 mm (9.8") / 183 mm (7.2")
M	250 mm (9.8") / 285 mm (11.2")
L	250 mm (9.8") / 415 mm (16.3")

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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 Reference FBDCSPAKSW7700END
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Dawn Cromwell
 Director, QA
 Laboratory, Food & Beverage

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.

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.

Pall Filtersystems GmbH confirm that the product manufacturing environment, for the above product at our Bad Kreuznach site, is in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

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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