

DECLARATION OF COMPLIANCE SUPRAPAK™ Depth Filter Modules SW Range “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
5200	
5300	
5500	
5600	
5700	
5800	SW Range
5900	
7000	
7100	
7300	

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

SUPRAPAK SW 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 FBDCSPAKSRENI
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 Quality Assurance & Regulatory Affairs Manager
 Pall Filtersystems GmbH

SUPRApak Depth Filter Modules (SW 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 sheet filter material consisting of cellulose, binder resin, Perlite, diatomaceous earth and polyolefin fibers

Declaration

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

Europe

The “W” Code SUPRApak SW 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).

Our suppliers state that the monomers and additives of the polyolefin fibers listed in European regulation (EU) Number 10/2011 Annex I.

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 (EU) Number 10/2011 Annex I 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 were 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

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 the lists in European Regulation (EU) Number 10/2011 Annex I and its amendments relating to plastic materials and articles intended to come into contact with foodstuffs.

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 (185 °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

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 use 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), in that:

- Polypropylene (with 20% talc) for the filter construction are listed in 21 CFR section 177.1520 (Olefin polymers), and the Polypropylene pigment is to 21 CFR section 178.3297 (colorants for polymers)
- Polyester (employed in the 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).
- Polyolefin fiber materials to 21 CFR section 177.1520 (Olefin polymers)
- 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.

The following are listed in the Food Chemical Codex (FCC): Perlite and diatomaceous earth

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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