

DECLARATION OF COMPLIANCE SUPRAPak™ Depth Filter Modules SR Range “W” Code

Module Part Number

SUPRAPAK SR 5100 W
Table 1

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

Table 1 : 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 (18.3")

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

SUPRAPak SR filter modules may be used for non-alcoholic as well as alcoholic beverages.

An initial flush is recommended prior to use.

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

SUPRApak Depth Filter Modules (SR5100 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, binder resin, perlite, diatomaceous earth and polyolefin fibers

Declaration

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

Europe

The “W” Code SUPRApak SR 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 are in accordance with the lists of materials 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) material used to make the hardware components are produced in accordance with the lists of materials and scoped in EU Regulation Number 10/2011 relating to plastic materials and articles intended to come into contact with foodstuffs.

Migration testing of the polypropylene (20% talc filled) components was performed in the following simulants for use after flushing and in flow conditions:

Simulant B (6% acetic acid) at 40 °C (104 °F) for 30 minutes

Simulant D1 (50% ethanol) at 40 °C (104 °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

- 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

A pigment in the Polypropylene is to BfR Recommendation IX

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 50% alcohol by volume, at temperatures not exceeding 49 °C (120 °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).
- 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 9001:2008

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.

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