

DECLARATION OF COMPLIANCE SUPRApak™ Depth Filter Modules SH Range “W” Code

Module Part Number

SUPRApak SH 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	Range
5300	SH Range
5700	
5900	
7200	

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

SUPRApak SH depth filter modules are intended especially for spirits filtration at up to 40 °C (104 °F). Additionally, these modules are suitable for filtration of high alcohol extracts.

An initial flush is recommended prior to use.

Issued 1 September 2009
 Revised 22 January 2021
 Expires 28 February 2023
 Reference FBDCSPAKSHENI
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Mario Basters
 Quality Assurance & Regulatory Affairs Manager
 Pall Filtersystems GmbH

SUPRApak Depth Filter Modules (SH Range “W” Code)

Components

Hardware

Tubular center core and Intermediate rings Polypropylene (20 % talc filled)

Attaching straps Polyester

Filter Media Seitz® depth filter material consisting of cellulose, binder resin, perlite, and diatomaceous earth and polyolefin fibers

Declaration

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

Europe

The “W” Code SUPRApak SH 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 fiber component material 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) 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) and polyester hardware components were 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

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 Annex I 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 talc (E 553b) and calcium stearate, which are approved as direct food additives.

Talc does not contain asbestiform fibers.

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

Mercosur

SUPRApak SH depth filter modules meet the requirements of food contact as detailed in Reglamento Técnico Mercosur sobre materiales celulósicos para cocción y filtración en caliente, Mercosur/GMC/Res. No. 41/15.

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 alcoholic 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 9001:2015.

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.

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