

DECLARATION OF COMPLIANCE SUPRAPAK™ Plus Depth Filter Modules PW Range “W” Code

Module Part Number

SUPRAPAK PW 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	SW Range
5500	
5700	
5900	
7100	

Table 2 : Nominal Dimensions

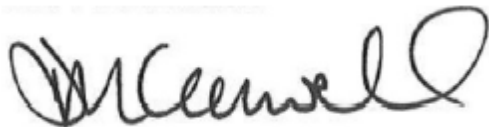
Code	Description
M	250 mm (9.8") / 285 mm (11.2")
L	250 mm (9.8") / 415 mm (16.3")

SUPRAPAK PW filter modules incorporate a variety of proprietary depth filter media in a convenient, disposable filter module, with polypropylene hardware.

SUPRAPAK PW 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 FBDCSPAKPWENb
 Page 1 of 3



Dawn Cromwell
 Director, QA
 Laboratory, Food & Beverage

SUPRApak Plus Depth Filter Modules (PW Range “W” Code)

Components

Hardware

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

Filter Media

Cellulose and binder resin
Perlite and diatomaceous earth
Polyolefin fibers

Declaration

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

• Europe

The “W” Code SUPRApak Plus PW 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). Additionally, the polyolefin fiber media component material employs monomers and additives listed in European Directive 10/2011/EC.

Migration testing of the filter media has been performed in Isooctane (as an oil replacement) for 2 hours at 60 °C (140 °F).

Additionally polyolefin fiber component materials have been extraction tested to German Recommendation XXXVI/1 with hot water at 85 °C (185 °F).

- Our suppliers state that the polypropylenes (natural and 20 % talc filled) used to make the hardware components are produced in accordance with the relevant requirements of Commission Regulation (EU) Number 10/2011 and its amendments. A pigment in the polypropylene is to BfR Recommendation IX (Pigments).

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

Simulant B (3 % acetic acid) at 100 °C (212 °F) for 120 minutes
 Simulant D1 (50% ethanol) at 70 °C (158 °F) for 120 minutes and at 60 °C (140 °F) for 2 days
 for all aqueous, acidic and alcoholic foods and milk products

Simulant D2 (olive oil) at 100 °C (212 °F) for 120 minutes, repeated use, for sealing lines and gasket

Additionally, migration testing of 20% talc filled polypropylene was performed in the following after flushing and in flow conditions:

6% acetic acid, at 85 °C (185 °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
 Sunflower oil, at 88 °C (190 °F) for 30 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)

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:

Bad Kreuznach, Germany

The Quality Management System at Pall 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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