PALL CORPORATION

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	PW Range
5300	
5500	
5700	
5900	
7100	
7300	
7700	

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

SUPRApak Plus PW filter modules may be used for non-alcoholic, alcoholic beverages and oils. Additionally, these modules are suitable for filtration of high alcohol extracts.

An initial flush is recommended prior to use.

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Reference	FBDCSPAKPWENi
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Pall Sàrl and MEA QARA Manager

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 Annex I, II and its amendments. A pigment in the polypropylene is to BfR Recommendation IX (Pigments).

OML and SML migration testing of the polypropylene (natural and 20 % talc filled) hardware components was performed and met migration criteria after flushing and in flow conditions in:

- 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, OML and SML migration testing of 20% talc filled polypropylene was performed and met migration criteria after flushing and in flow conditions in:

- 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

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

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. Talc does not contain asbestiform fibers.

Mercosur

SUPRApak Plus PW 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.

The materials of construction meet the requirements for food contact as detailed in Reglamento Técnico Mercosur sobre materiales lista positiva de

- monómeros, otras substancias de partida y polímeros autorizado para la elaboración de envases y equipamientos plásticos in contacto con alimentos, Mercosur/GMC/Res. No. 19/21 y
aditivos para materiales plásticos destinados a la elaboración de envases y equipamientos in contacto con alimentos, Mercosur/GMC/Res. No 56/92.

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: Manufactured in Germany and supplied by Pall Sàrl. Made in Germany

The Quality Management System at the manufacturing site 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 Sàrl confirms 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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Pall Corporation has offices and plants throughout the world. To locate the Pall office or distributor nearest you, visit www.pall.com/contact.

The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

IF APPLICABLE Please contact Pall Corporation to verify that the product conforms to your national legislation and/or regional regulatory requirements for water and food contact use..

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