PALL CORPORATION

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

Module Part Number

SUPRApak ZD ☐ ☐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	ZD Range
5500	
5900	

Table 2 : Nominal Dimensions

Code	Description (Length / Diameter)
M	250 mm (9.8”) / 285 mm (11.2”)
L	250 mm (9.8”) / 415 mm (16.3”)

SUPRApak ZD depth filter modules incorporate a variety of appropriate depth filter media in a convenient, disposable filter module, with Polypropylene hardware and Polyester straps.

SUPRApak ZD filter modules can be used for non-alcoholic and alcoholic beverages as well as applications including sweeteners, sugar syrups, enzymes, flavors and edible 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 FBDCSPAKZDENe

Mario Basters
Quality Assurance & Regulatory Affairs Manager
Pall Filtersystems GmbH

SUPRApak Depth Filter Modules (ZD 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 and binder resin

Declaration

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

Europe

The "W" Code SUPRApak ZD 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).

  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 and other components are produced in accordance with the lists of materials in EU Regulation (EU) Number 10/2011 Annex I relating to plastic materials and articles intended to come into contact with foodstuffs.

  A pigment in the Polypropylene is compliant to BfR Recommendation IX.

  OML Migration testing of the Polypropylene (20% talc filled) and Polypropylene material used to make the hardware components were performed in the following simulants for use after flushing and in flow conditions:

  Simulant B (3% Acetic acid) at 70 °C for 2 hours and

  Simulant D1 (50% Ethanol) at 70 °C for 2 hours

- 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 ºC (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.
Talc does not contain asbestiform fibers.

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

Mercosur

SUPRApak ZD 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, in that:

- 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)
- Total filter sheet material extractable as per 21 CFR section 177.2260 (Filters, resin bonded) (g) (h) (i) (j) (k) (l)
- 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 strap) to 21 CFR section 177.1630 (Polyethylene Phthalate polymers)

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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