

DECLARATION OF COMPLIANCE SUPRAdisc™ II Depth Filter Modules IR Range “W” Code

Module Part Number

200 C P W
Table 1 Table 2 Table 3

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

Table 1 : Sheet Media Type

Code	Description
C100	K100IR
C250	K250IR
C800	K800IR

Table 2 : Dimensions

Code	Nominal Diameter	# of Sheets	Area
232	287 mm (12")	32	1.8 m ² (19.4 ft ²)
440	410 mm (16")	40	5 m ² (54 ft ²)

Table 3 : Flat Gasket Options

Code	Description
S	Silicone (standard)
E	Ethylene Propylene Rubber

SUPRAdisc II IR depth filter modules are intended for cold filtration of foodstuffs. These 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 FBDCSDISCIRENh
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Mario Basters
 Quality Assurance & Regulatory Affairs Manager
 Pall Filtersystems GmbH

SUPRAdisc II Depth Filter Modules (IR Range “W” Code)

Components

Hardware	Polypropylene
Filter Media	Cellulose, binder resin, perlite, diatomaceous earth and polyolefin fibers
Gasket	Silicone Elastomer (S) or Ethylene Propylene Rubber (E)

Declaration

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

Europe

The “W” Code SUPRAdisc IR 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 in European Regulation (EU) Number 10/2011 Annex I.

- Our suppliers state that the polypropylene used to make the hardware components are produced in accordance with the lists scoped in European Regulation (EU) 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 hardware components was performed in the following simulants after flushing and in flow conditions:

Simulant B (6 % Acetic Acid) for 30 minutes at 40 °C (104 °F)

Simulant D1 (50 % Ethanol) for 30 minutes at 40 °C (104 °F).

Note:

This product contains polypropylene that is subject to Specific Migration Limit (SML) requirements.

This product contains calcium stearate, which is approved as a direct food additive.

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

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:

- Polypropylene (employed hardware) to 21 CFR section 177.1520 (Olefin 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)
- Ethylene Propylene Rubber and Silicone Elastomeric seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils)

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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