

DECLARATION OF COMPLIANCE

SUPRAdisc™ II Depth Filter Modules

IR Range “W” Code

Module Part Number

200 P W

Table 1 Table 2 Table 3 Table 4

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 : Adaptor

Code	Diameter
C	Flat Gasket
S	Double O-ring

Table 3 : 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 4 : 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 and alcoholic beverages. Additionally, these modules are suitable for filtration of high alcohol extracts.

An initial flush is recommended prior to use.

Issued 1 May 2010
 Revised 15 July 2023
 Expires 28 February 2025
 Reference FBDCSDISCIRENI
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 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 II 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 and II.

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 II and its amendments relating to plastic materials and articles intended to come into contact with foodstuffs.

OML and SML migration testing of the polypropylene hardware components was performed and met migration criteria after flushing and in flow conditions in:

- Simulant B (3 % 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.

Mercosur

The SUPRAdisc II IR 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 sustancias de partida y polímeros autorizado para la elaboración de envases y equipamientos plásticos in contacto con alimentos, Mercosur/GMC/Res. No. 02/12 y
- aditivos para materiales plásticos destinados a la elaboración de envases y equipamientos in contacto con alimentos, Mercosur/GMC/Res. No 39/19.

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 supplied by Pall Sàrl. Made in Germany.

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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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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JULY 2023