

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

Module Part Number

200 D C 420 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 Series

Code	Description
X	K Series
C	IR Series

Table 2 : Sheet Media Type

Code	Top Sheet Pre-Filter	Bottom Sheet Fine Filter
K Series		
O7	K900	K150
O8	K900	K200
N6	K800	K100
N7	K800	K150
M5	K700	KS80
M6	K700	K100
L4	K300	KS50
L5	K300	KS80
L6	K300	K100
L7	K300	K150
K3	K250	EK
K4	K250	KS50
H2	K200	EK1
H3	K200	EK
H5	K200	KS80
G1	K150	EKS
G2	K150	EK1
G5	K150	KS80
F1	K100	EKS
F2	K100	EK1
F3	K100	EK
IR Series		
N4	K800IR	KS50IR
N6	K800IR	K100IR
N9	K800IR	K250IR
K4	K250IR	KS50IR
K6	K250IR	K100IR
F4	K100IR	KS50IR

Table 3 : Flat Gasket Options

Code	Description
S	Silicone (standard)
E	Ethylene Propylene Rubber

SUPRAdisc II HP 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.

Issued 1 May 2010
 Revised 1 February 2019
 Expires 28 February 2021
 Reference FBDCSDISCHPENi
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Mario Basters
 Quality Assurance & Regulatory Affairs Manager
 Pall Filtersystems GmbH

SUPRAdisc II Depth Filter Modules (HP 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 HP depth filter modules comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

Europe

The “W” Code SUPRAdisc HP 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 employs monomers and additives are listed in Annex I of Commission Regulation (EU) Number 10/2011 and its amendments.

- Our suppliers state that the monomers and additives of the polypropylenes used to make the hardware components are consistent with Annex I of Commission Regulation (EU) Number 10/2011 and its amendments, relating to plastic materials and articles intended to come into contact with foodstuffs.

Migration testing of the polypropylene hardware components was carried out in 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.

Supplied in Europe by

Pall International Sàrl
Av. de Tivoli 3
Fribourg
Switzerland
CH-1700




Pall Food and Beverage

New York - USA
+1 516 484 3600 telephone
+1 866 905 7255 toll free
foodandbeverage@pall.com

Visit us on the web at www.pall.com

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