

DECLARATION OF COMPLIANCE SUPRAdisc™ II Depth Filter Modules

K Range "W" Code

Module Part Number

200 Table 1 Table 2 Table 3 Table 4 P W

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

Table 1: Sheet Media Type

Code	Description
XEKS	EKS
XEK1	EK1
XEKO	EK
X050	KS50
X080	KS80
X100	K100
X150	K150
X200	K200
X250	K250
X300	K300
X700	K700
X800	K800
X900	K900

Table 2: Adaptor

Code	Diameter
С	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 K 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 applications including sweeteners, sugar syrups and high alcohol extracts.

An initial flush is recommended prior to use.

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Mario Basters Quality Assurance & Regulatory Affairs Manager Pall Filtersystems GmbH

SUPRAdisc II Depth Filter Modules (K Range "W" Code)

Components

Hardware Polypropylene

Filter Media Cellulose, binder resin, perlite, diatomaceous earth and polyolefin fibers

Gasket Silcone elastomer (S) or Ethylene Propylene Rubber (E)

Declaration

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

Europe

The "W" Code SUPRAdisc K 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.

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 K 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. 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:

• 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)
 (i) (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 Modultechnik 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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