

DECLARATION OF COMPLIANCE MICROsorp OC Filter Cartridges “W” Code

Cartridge Part Number

469 A080 W SP
Table 1 Table 2

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

Table 1 : Adaptor

Code	Description
3	SOE – single open end with flat closed end and external 222 O-rings
7	SOE – single open end with fin end, 2 locking tabs and external 226 O-rings
41	SOE – single open end with fin end, 3 locking tabs and external 222 O-rings

Table 2 : Nominal Length

Code	Description
1	254 mm (10")
2	508 mm (20")
3	762 mm (30")
4	1016 mm (40")

The MICROsorp OC filter has a filter medium layer (comprised of resin-bonded liquid crystal fibers on a cellulose substrate) and polypropylene non-woven support and drainage materials in a polypropylene hardware configuration.

This filter is intended for the pre-filtration of water.

An initial flush is recommended prior use.

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 Reference FBDCMICOCENa
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Mario Basters
 Quality Assurance & Regulatory Affairs Manager
 Pall Filtersystems GmbH

MICROsorp OC Filter Cartridges (“W” Code)

Components

Filter Medium	Resin bonded liquid crystal fibers on a cellulose substrate
Support / Drainage, Side Seal Clip Core, End Cap and Fin End, Cage	Polypropylene
Adaptor	Polypropylene with internal stainless steel reinforcing ring as appropriate to design*
O-ring Seal	Silicone Elastomer (S)

*For applications requiring autoclaving or steam sterilization, Pall recommends the use of Code 07 adaptors to ensure filter sealing after cooling. Cartridges should be cooled to system operating temperature prior to use.

Declaration

MICROsorp OC “W” Code filter cartridges comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

Europe

The “W” Code MICROsorp OC filters meet the requirements for food contact, in that:

- The filter medium of this product is composed of two or more layers of material, one of which does not consist exclusively of plastics. The plastic components of this medium meet the requirements listed in Commission Regulation (EU) Number 10/2011 on plastic materials and articles intended to come into contact with foodstuffs.
- The cellulose substrate material complies with European Regulation (EC) Number 1935/2004.
- The polypropylene end caps, cage, core, adaptor and fin of this product - together with the polypropylene support/drainage layer - meet the requirements scoped in Commission Regulation (EU) Number 10/2011, and its amendments, on plastic materials and articles intended to come into contact with foodstuffs.

Overall migration testing of a469A080W071SP filter was conducted, and met migration criteria after flushing and in flow conditions, in:

Simulant A (10% ethanol), for 2 hours at 100 °C (212 °F)

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.
This product employs a BADGE resin.

- Samples of the silicone elastomeric (H4) seal material formulations, typically used with the above part numbers, have been tested as 226 size seals for overall migration. Testing was conducted in distilled water, 3% acetic acid and 20% ethanol, under reflux conditions for 4 hours - repeat use. In respect of the overall migration limit for food contact elastomers according to the French requirements (given in Arrete of November 9th 1994 and published in Journal Officiel de la Republique Francaise, December 2nd 1994, p17029-17036) is 10 mg/dm², data obtained with the rubber o-rings under the tested conditions was well within this limit.

The volatile levels from samples of the silicone elastomer (S) formulation, after heating at 200° C (392 °F) for 4 hours, was found to be within the BfR section XV specification for this material.

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

USA

- The liquid crystal fibers have an FCN Number 174.

The following 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:

- Resin binder material to 21 CFR section 175.105 (Adhesives)
- Resin component to 21 CFR section 176.170 (Components of paper and paperboard in contact with aqueous and fatty foods)
- Cellulose substrate material to 21 CFR section 176.170 (Components of paper and paperboard in contact with aqueous and fatty foods)
- Polypropylene to 21 CFR section 177.1520 (Olefin polymers)
- Silicone Elastomeric seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils)

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 the product manufacturing environment, for the above product at our Bad Kreuznach site, is 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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