

DECLARATION OF COMPLIANCE MICROsorp OC Filter Cartridges

“W” Code

Cartridge Part Number

469 A080 W ☐ ☐ ☐ P

Table 1 Table 2 Table 3

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

Table 1 : Adaptor

Code	Description
02	SOE – single open end with flat closed end and external 226 O-rings
03	SOE – single open end with flat closed end and external 222 O-rings
07	SOE – single open end with fin end, 2 locking tabs and external 226 O-rings
28 or 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")

Table 3 : O-Ring Seal Material

Code	Description
S	Silicone Elastomer
E	Ethylene Propylene Rubber

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 and wine.

An initial flush is recommended prior use.

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Reference FBDCMICOCENh
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Syed Sirajuddin
Pall Sàrl and MEA QARA Manager

MICROsorp OC Filter Cartridges ("W" Code)

Components

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

*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.

SML and OML migration testing of 469A080W071SP filter was performed, and met migration criteria after flushing and in flow conditions, in:

- Simulant A (10 % ethanol) for 2 hours at 100 °C (212 °F)
- Simulant B (3 % acetic acid) for 2 hours at 100 °C (212 °F)
- Simulant D1 (50 % ethanol) for 2 days at 60 °C (140 °F)
- And water up to 70 °C (158 °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.

French requirements for food contact elastomers (Arrêté of 9th November 1994 amended by order of 5th August 2020) Typical samples of the 'S' (Silicone) and 'E' (EPDM) seal material formulations have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 20 % ethanol, 50 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the 'S' O-rings, under the test conditions, were well within the limit for all migration fluids tested. The data obtained with the 'E' O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid, 20 % ethanol and 50 % ethanol. The 'E' O-rings are not suitable for use in fatty foods.

German requirements for food contact elastomers (BfR XV Silicones) Typical samples of the 'S' (Silicone) seal material formulation have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 10 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the 'S' O-rings, under the test conditions, were well within the limit for all migration fluids tested.

German requirements for food contact elastomers (BfR XXI Natural and Synthetic Rubber Category 1) Typical samples of the 'E' (EPDM) seal material formulation have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 10 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the 'E' O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid and 10 % ethanol. The 'E' O-rings are not suitable for use in high alcohol or fatty foods. Additionally, our supplier states that this O-ring seal formulation is suitable for food contact use under BfR XXI category 4.

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

Mercosur

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. 19/21 y
- aditivos para materiales plásticos destinados a la elaboración de envases y equipamientos in contacto con alimentos, Mercosur/GMC/Res. No. 56/92.

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)
- Ethylene Propylene Rubber seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use with aqueous foods, excluding fatty foods (e.g. milk and edible oils)) based on confirmatory testing as detailed in section (e).
- Silicone Elastomer seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use, with aqueous and fatty foods (e.g. milk and edible oils) based on confirmatory testing as detailed in sections (e, f).

Process Quality System

Site of Manufacture: Manufactured in Germany and supplied by Pall Sàrl. Made in Germany

The Quality Management System at the manufacturing site 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 Sàrl confirms 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 Sàrl
Av. de Tivoli 3
Fribourg
Switzerland
CH-1700



+1-866-905-7255 **Food and Beverage toll free**
foodandbeverage@pall.com

Corporate Headquarters

Port Washington, NY, USA
+1-800-717-7255 toll free (USA)
+1-516-484-5400 phone

European Headquarters

Fribourg, Switzerland
+41 (0)26 350 53 00 phone

Asia-Pacific Headquarters

Singapore
+65 6389 6500 phone

Pall Corporation has offices and plants throughout the world. To locate the Pall office or distributor nearest you, visit www.pall.com/contact.

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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