

DECLARATION OF COMPLIANCE
PREcart LCF Filter Cartridges
AB Style "W" Code

Cartridge Part Number

AB  LCF 7 W H4

Table 1

Table 1 : Nominal Length

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

The PREcart LCF filter employs a Pall proprietary filter medium layer (comprised of resin-bonded fluid lattice polymer fibers on a cellulose substrate) and polyester non-woven support and drainage materials in a polypropylene hardware configuration, for use up to 49 °C (120 °F).

This filter is intended for pre-filtering of wine.

An initial flush is recommended prior use.

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Reference FBDCPRELCFENe
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PREcart LCF Filter Cartridges (AB Style “W” Code)

Components

| | |
|---------------------------|--|
| Filter Medium | Resin bonded fluid lattice polymer fibers on a cellulose substrate |
| Support / Drainage | Polyester non-woven |
| Side Seal Clip | Polypropylene |
| Cage | Polypropylene with TiO ₂ colorant |
| Core, End Cap and Fin End | Polypropylene |
| Adaptor | Polypropylene with an internal stainless steel reinforcing ring |
| O-ring Seal | Silicone elastomer |

Declaration

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

Europe

The “W” Code PREcart LCF filters meet the requirements of European Regulation (EC) number 1953/2004, 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.
- Our supplier information indicates that the cellulose substrate material complies with Regulation (EC) number 1935/2004.
- Our supplier information indicates that the polypropylene end caps, cage, core, adaptor and fin of this product - together with the polyester support/drainage layer – are made from monomers and additives listed in Annex I of European Commission Regulation (EU) number 10/2011, and its amendments, related to plastic materials and articles intended to come into contact with foodstuffs.
- Overall migration testing, of a filter using identical materials of constructions and production methods to a PREcart LCF filter, was conducted in Simulant B (3% acetic acid) and Simulant C (20% ethanol), under exposure conditions of 2 hours at 70 °C (158 °F), and met migration criteria after flushing and in flow conditions.
- Samples of the silicone elastomeric (H4) seal material formulation, 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 10 mg/dm² 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) the data obtained was well within this limit.

The volatile levels from samples of the silicone elastomer (H4) formulation, after heating at 200 °C (392 °F) for 4 hours, was found to be within the BfR section XV specification for this material.

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.

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

USA

The liquid crystal fibers employed have 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).
- Polyester to 21 CFR section 177.1630 (Polyethylene phthalate polymers) for bulk filtration up to 49°C.
- Polypropylene to 21 CFR section 177.1520 (Olefin polymers).
- Silicone elastomeric seal material to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils).

Process Quality System

Site of Manufacture: Pall Manufacturing (UK) Ltd., Ilfracombe, UK on behalf of Pall International Sàrl.

The Quality Management System at Pall Manufacturing (UK) Ltd., Ilfracombe, 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 Pall Manufacturing (UK) Ltd., Ilfracombe, confirm that the product manufacturing environment, for the above product, is in-line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

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