

DECLARATION OF COMPLIANCE
Ultipleat® High Flow Filter Elements
CAS Series “W” Code

Element Part Number

HFU 6  CAS010 J U W
Table 1

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

Table 1 : Nominal Length

| Code | Description |
|-------------|--------------------|
| 20 | 508 mm (20") |
| 40 | 1016 mm (40") |
| 60 | 1524 mm (60") |

The Ultipleat CAS High Flow Filter element is a large diameter, disposable, pleated, filter cartridge for high flow rates in water, with an inside-to-outside flow pattern.

The filter is intended for use in food and beverage water filtration applications at up to 50 °C (122 °F). Additionally, the filter elements may be utilized in spirits filtration applications up to 40 °C (104 °F).

An initial flush is recommended prior to use.

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Ultipleat High Flow Filter Elements (CAS Series “W” Code)

Components

| | |
|-----------------------------|--|
| Filter Media | Pall proprietary Supor [®] polyethersulfone membrane and proprietary melt blown polypropylene Profile [®] UP media |
| Support Mesh and Outer Wrap | Polypropylene |
| Wrap Adhesive | Hot air bonding |
| End Caps and Handle | White (TiO ₂ filled) colored polypropylene moldings (10 % glass reinforced) |
| Seal | Ethylene Propylene Rubber (JUW option) |

Declaration

Ultipleat High Flow CAS Series filter elements comprise materials that meet regulatory and legislative requirements and guidelines for food contact in that:

Europe

The "W" Code Ultipleat CAS High Flow Filter Elements meet the requirements for aqueous food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

Our suppliers' information indicates that the plastic components employed are made from monomers and additives 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.

Overall Migration Limit testing of HFU hardware components, support mesh and media pack has been performed after flushing and in flow conditions (excluding seals) in:

Simulant A (10 % ethanol) at 100 °C (212 °F) for 4 hours
 Simulant B (3 % acetic acid) at 100 °C (212 °F) for 4 hours
 Simulant D1 (65 % ethanol) at 40 °C (104 °F) for 2 hours
 Distilled water at 70 °C (158 °F) for 2 hours

SML testing of support mesh material, media pack and CAS010 membrane has been performed after flushing and in flow conditions in:

Simulant A (10 % ethanol) at 100 °C (212 °F) for 4 hours
 Simulant B (3 % acetic acid) at 100 °C (212 °F) for 4 hours
 Simulant D1 (65 % ethanol) at 40 °C (104 °F) for 2 hours
 Distilled water at 70 °C (158 °F) for 2 hours

Note: This product contains materials that are subject to SML requirements. This product contains calcium stearate, which is approved as a direct food additive.

Glass fibers are approved as an additive to plastic within Regulation 10/2011 under reference number 55520.

Samples of the Ethylene Propylene Rubber seal material formulation have been tested in the JUW format as utilized on this product for overall migration. Testing was conducted in distilled water, 3% acetic acid, 20 % ethanol and 50 % 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 amended by order of 5th August 2020) is 10 mg/dm², data obtained with the rubber o-rings under the tested conditions were well within this limit.

Additionally, testing to BfR XXI Natural and Synthetic rubber (Category 1) has shown this material formulation is well within the overall migration limit of 50 mg/dm² for distilled water and 10 % ethanol and 150 mg/dm² for 3 % acetic acid.

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. 02/12 y
- aditivos para materiales plásticos destinados a la elaboración de envases y equipamientos in contacto con alimentos, Mercosur/GMC/Res. No32/07.

USA

The thermoplastic filter components, with the exception of the glass-filler in the molded end caps, meet the FDA requirements for food contact use as detailed in Code of Federal Regulations, 21CFR paragraphs 170-199 in that:

- The molded end caps utilize glass filler to enhance strength and maintain dimensional stability. The fibers are considered encapsulated by the endcap base resin.
- Polypropylene to 21CFR section 177.1520 (Olefin polymers) and section 178.2010 (antioxidants and/or stabilizers or polymers).
- Typical Supor membranes were analyzed as per ASTM test methods for conformance to FDA specifications for food contact substances. The membranes met the specifications for polyethersulfone resins as described in Title 21 of the U.S. Code of Federal Regulations 177.2440, paragraphs (a), (b) and (c) including acceptable heavy metal content. Additionally, no specified or known adjuvants were detected at a limit of 0.001%.
- Ethylene Propylene Rubber seal material to 21CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils)

Note: this product may contain trace levels of titanium dioxide, a chemical known to the state of California to cause cancer. The listing for titanium dioxide is for “airborne, unbound particles or respirable size.” The listing is not applicable to titanium dioxide within a product matrix such as polypropylene.

Process Quality System

Site of Manufacture: Pall Cortland, USA.

The Quality Management System at Pall Cortland 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 Cortland confirms that the 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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