

DECLARATION OF COMPLIANCE

Ultipleat® High Flow Filter Elements

UY Series “W” Code

Element Part Number

HFU 6 J U W
Table 1 Table 2

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")

Table 2 : Removal Rating

Code	Description
UY020	2 µm
UY045	4.5 µm
UY100	10 µm
UY200	20 µm
UY400	40 µm

The Ultipleat High Flow filter element is a disposable, pleated, coreless filter designed to process aqueous and low acid food products, at temperatures up to 50 °C (122 °F) at high flow rates. 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 (UY Series “W” Code)

Components

Filter Media	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)
O-ring Seal	Ethylene Propylene Rubber (EPR)

Declaration

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

Europe

The “W” Code UY Series Ultipleat High Flow filter elements meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

Our suppliers’ information indicates that the polymeric materials used to produce “W” Code UY Series Ultipleat Profile type products employing Profile UP media 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 Profile UP filter media, HFU hardware components and support mesh 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 and media pack 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 listed as an additive to plastic within European Regulation 10/2011 under reference 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 are 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 contact use as detailed in Code of Federal Regulations, 21 CFR paragraphs 170-199 in that:

- The molded end caps utilize a glass-filler to enhance the strength and maintain dimensional stability.
- Polypropylene to 21 CFR section 177.1520 (Olefin polymers) and section 178.2010 (antioxidants and/or stabilizers for polymers)
- 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)

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.

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