

DECLARATION OF COMPLIANCE Ultipor® N66 Filter Cartridges

AB Style “W” Code with Polyester Hardware

Cartridge Part Number



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

Table 1 : Nominal Length

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

Table 2 : Removal Rating

| Code | Description | Membrane Layers |
|------|-------------|-----------------|
| NF | 0.2 µm | 2 |
| NA | 0.2 µm | 1 |
| NL | 0.45 µm | 2 |
| NB | 0.45 µm | 1 |
| NK | 0.65 µm | 1 |
| NH | 0.8 µm | 1 |
| NN | 1.2 µm | 1 |
| NNN | 1.2 µm | 2 |

Table 3 : 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 |
| 8 | SOE – single open end with fin end and external 222 O-rings |
| 28 | SOE – single open end with fin end, 3 locking tabs and external 222 O-rings |

Table 4 : O-Ring Seal Material

| Code | Description |
|------|---------------------------|
| H4 | Silicone Elastomer |
| J | Ethylene Propylene Rubber |

The product comprises of Pall proprietary Ultipor N66 filter medium with integral polyester non-woven support in a disposable filter cartridge using polypropylene and polyester hardware.

For use in water up to 70 °C (158 °F) and bulk alcoholic beverages in low alcoholic applications (such as wine and beer) at temperatures up to 49 °C (120 °F). The materials of construction do not contain surfactants or binder resins.

An initial flush is recommended prior to use.

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 Page 1 of 3



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Ultipor N66 Filter Cartridges (AB Style “W” Code with polyester hardware)

Components

| | |
|---------------------|---|
| Filter Media | Ultipor N66 – nylon with integral polyester non-woven substrate |
| Support / Drainage | Polyester |
| Cage and Core | Polypropylene |
| End Cap and Fin End | Polyester |
| Adaptor | Polyester |
| O-ring Seal | Ethylene Propylene Rubber (J) or Silicone Elastomer (H4) |

Declaration

Ultipor N66 AB “W” Code style filter cartridges comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

Europe

The “W” Code Ultipor N66 AB filter cartridges 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 Ultipor N66 filters are made from monomers and additives consistent with Annexes I and II of Commission Regulation (EU) Number 10/2011 and its amendments, relating to plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

OML and SML migration testing (excluding seals) performed on the materials of construction, and met migration requirements in after flushing and in flow conditions, as appropriate in:

- Simulant A (10% ethanol)
- Simulant B (3% acetic acid)
- Simulant C (20% ethanol)
- and distilled water.

Component testing gave a maximum temperature limit of 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.

French requirements for food contact elastomers (Arrêté of 9th November 1994 amended by order of 5th August 2020) Typical samples of the ‘H4’ (Silicone) and ‘J’ (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 ‘H4’ O-rings, under the test conditions, were well within the limit for all migration fluids tested. The data obtained with the ‘J’ O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid, 20 % ethanol and 50 % ethanol. The ‘J’ O-rings are not suitable for use in fatty foods.

German requirements for food contact elastomers (BfR XV Silicones) Typical samples of the ‘H4’ (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 ‘H4’ 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 ‘J’ (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 ‘J’ O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid and 10 % ethanol. The ‘J’ 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.

USA

The materials of construction meet the FDA requirements for food contact use, in water up to 70 °C (158 °F), and for bulk alcoholic beverages in low alcoholic applications up to 49 °C (120 °F) as detailed in Code of Federal Regulations, 21 CFR paragraphs 170-199 in that:

- Nylon N66 to 21 CFR section 177.1500 (Nylon resins)
- Polypropylene to 21 CFR section 177.1520 (Olefin polymers)
- Polyester to 21 CFR section 177.1630 (Polyethylene phthalate polymers) and 21CFR177.1660 (Polytetramethylene terephthalate)
- 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)

Process Quality System

Site of Manufacture: Pall Manufacturing (UK) Ltd., Ilfracombe, UK supplied by Pall Sàrl. Made in UK.

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

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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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