

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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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 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 (excluding seals).

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.

- Typical samples of the ‘H4’ and ‘J’ 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 and 50% ethanol, under reflux conditions for 4 hours - repeat use. In respect of the overall migration limit of 10 mg/dm², as given in French requirements for food contact elastomers (Arrêté of November 9th 1994 and published in Journal Officiel de la Republique Française, December 2nd 1994, p17029-17036) the data obtained with the rubber o-rings, under the tested conditions, was well within the limit).
- Our supplier states that the ‘J’ ethylene propylene rubber material employed conforms to BfR XXI Category 4 requirements.
- Our supplier states that the ‘H4’ silicone elastomer material employed conforms to BfR XV requirements.

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 on behalf of Pall International Sàrl.

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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