

DECLARATION OF COMPLIANCE

Ultipor® N66 Filter Cartridges

MCY Junior Style “W” Code

Cartridge Part Numbers

MCY W H4
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	Length	Description
1110	32 mm (1.3")	Plug seal adaptor with locating fin and double external O-ring seals
2220	57 mm (2.2")	Plug seal adaptor with locating fin and double O-ring seals
4440	105 mm (4.2")	Plug seal adaptor with locating fin and double external O-ring seals
4463	127 mm (5.3")	Single 116 O-ring Seal and internal plug seal

Table 2 : Removal Rating

Code	Description	Membrane Layers
NF	0.2 µm	2
NA	0.2 µm	1
NB	0.45 µm	1

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 in low alcoholic applications at temperatures up to 49 °C (120 °F).

An initial flush is recommended prior to use.

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Ultipor N66 Filter Cartridges (Junior Style “W” Code)

Components

Filter Media	Ultipor N66 – nylon with integral polyester non-woven substrate
Support / Drainage	Polyester
Core / Cage	Polypropylene
End Cap	Polyester
O-ring Seal	Silicone Elastomer (H4)

Declaration

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

Europe

The “W” Code Ultipor N66 Junior style 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 Junior 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 of MCY4463NFWH4 style Ultipor N66 filter cartridges (excluding seals) / materials of construction has been performed as appropriate, in:

Simulant A (10% ethanol),
Simulant B (3% acetic acid) and
Simulant C (20% ethanol).

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 République 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)
- Polypropylenes to 21 CFR section 177.1520 (Olefin polymers)
- Polyesters to 21 CFR section 177.1630 (Polyethylene phthalate polymers) and 21CFR177.1660 (Polytetramethylene terephthalate)
- 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 ISO9001:2015

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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