

DECLARATION OF COMPLIANCE Pasteurizer Replacement Filter Cartridges AB Style "W" Code

Cartridge Part Numbers

Table 1 : Pre-Filters

Part Number	Media and hardware description
AB4PAREG7WH4	All polypropylene media and hardware construction.
AB4PAREJ7WH4	All polypropylene media and hardware construction.

Table 2 : Final Membrane Filters

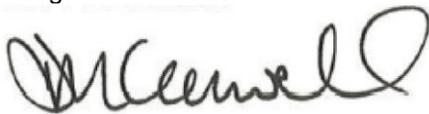
Part Number	Media and hardware description
ABN4PAREM7WH4	Nylon 6:6 filter media in a Nylon 6-10 filter construction.
AB4PAREQ7WH4	Supor® polyethersulfone filter membrane in a polypropylene filter construction.
ABN4PAREV7WH4	Nylon 6:6 filter media in a Nylon 6-10 filter construction.
ABN4PAREY7WH4	Nylon 6:6 filter media in a Nylon 6-10 filter construction.

The Pasteurizer Replacement filter cartridges are manufactured from a variety of materials detailed in Tables 1 and 2 above.

The Pasteurizer Replacement filter cartridges are suitable and intended for use in beer applications.

An initial flush is recommended prior to use.

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Pasteurizer Replacement Filter Cartridges (AB Style “W” Code)

Components

Filter Media	Q: Supor polyethersulfone (Hydrophilic) membrane G/J: Polypropylene M/V/Y: Nylon 6:6 with integral polyester non-woven substrate
Drainage / Support	Q/G/J: Polypropylene M/V/Y: Polyester
Cage, Core,	Polypropylene
End Cap and Fin End	Q/G/J: Polypropylene M/V/Y: Unpigmented Nylon 6-10
Adaptor	Q/G/J: Polypropylene with an internal stainless steel reinforcing ring M/V/Y: Unpigmented Nylon 6-10 with integral stainless steel reinforcing ring
O-ring Seal	Silicone Elastomer (H4)

Declaration

Pasteurizer Replacement AB 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 Pasteurizer Replacement filter cartridges meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

For All:

- Our suppliers state that the polymeric materials of construction 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).

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.

Users should satisfy themselves that these materials are suitable for use in their specific food application.

For Q and G:

Migration testing has been performed on sample filters (excluding seals), and met migration criteria after flushing and in flow conditions in:

Simulant B (3% acetic acid), 30 mins at 40 °C (104 °F) and
Simulant D1 (50% ethanol), 30 mins at 40 °C (104 °F)

- Our supplier states that the ingredients of the silicone elastomeric material employed are in compliance with Recommendation XV of the BfR and Arrete du 25 Novembre 1992.

For M, V, Y, and J:

Migration testing of the filters and components has been performed, and met migration criteria after flushing and in flow conditions in:

Simulant A (10% ethanol)
Simulant B (3% acetic acid)
And also in distilled water.

In addition, migration testing of the AB hardware and media materials have been performed for 2 hours at 100 °C in Simulant C (20% ethanol).

Samples of the silicone elastomeric (H4) seal formulation, typically used with the above part numbers, have been tested as 226 size seals for overall migration. Testing was conducted in distilled water, 3% acetic acid, and 20% 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 published in Journal Officiel de la Republique Francaise, December 2nd 1994, p17029-17036) is 10 mg/dm², data obtained with the rubber o-rings under the tested conditions was well within this limit.

The volatile levels from samples of the silicone elastomer (H4) formulation, after heating at 200 °C for 4 hours, was found to be within the BfR section XV specification for this material.

For M, V, Y:

Migration testing of the filters and components has been performed, and met migration criteria after flushing and in flow conditions in:

Component testing gave a maximum temperature limit of 70 °C (158 °F).

USA

The raw materials of construction meet the FDA requirements for food contact use as detailed in Code of Federal Regulations, 21 CFR paragraphs 170-199 in that:

- Polypropylene to 21 CFR 177.1520 (Olefin polymers)
- Polyethersulfone to 21CFR 177.2440 (Polyethersulfone resins)
- Nylon N66 and Nylon 6-10 to 21 CFR section 177.1500 (Nylon resins)
- Polyesters to 21 CFR section 177.1630 (Polyethylene phthalate polymers) and 21 CFR 177.1660 (Poly tetramethylene terephthalate)
- Silicone elastomeric seals to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils).

Process Quality System

These products / packaging carry a lot number / date code to facilitate traceability to suppliers' materials and Pall production records.

For Q and G:

Site of Manufacture: Pall Filtersystems GmbH, Bad Kreuznach, Germany on behalf of Pall International Sàrl.

The Quality Management System at Pall Filtersystems GmbH, Bad Kreuznach, is certified to ISO 9001:2008.

These products / product packaging carry a lot number / date code to facilitate traceability to suppliers' materials and Pall production records.

For M, V, Y, and J:

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 ISO 9001:2008. Pall Manufacturing (UK) Ltd., Ilfracombe, confirm that the product manufacturing environment, for the above products at our site, is in-line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

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