



DECLARATION OF COMPLIANCE Imperium™ Microbial Stabilization Filter Cartridges Imperium Style “W” Code

Cartridge Part Number

IMPCMSBDWH4

The Imperium Microbial Stabilization filter cartridges each use a single layer of Supor® polyethersulfone (PES) filter membrane in a polypropylene filter construction.

Imperium Microbial Stabilization filters are suitable for microbial control in aqueous-based, slightly alcoholic food and beverage products, such as beer, wine and bottled water.

An initial flush is recommended prior use.

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Imperium Microbial Stabilization Filter Cartridges (Imperium style “W” Code)

Components

Filter Membrane	One layer of hydrophilic Supor polyethersulfone membrane
Support / Drainage	Polypropylene
Cage, Core, End Cap and Handle	Polypropylene with talc* and titanium dioxide filler
Adaptor	Polypropylene with talc* and titanium dioxide filler and a stainless steel reinforcing ring
O-ring Seal	Silicone Elastomer (H4)

* Note – talc does not contain asbestiform fibres

Declaration

Imperium Microbial Stabilization “W” Code filter cartridges comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

Europe

The “W” Code Imperium Microbial Stabilization 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 Imperium Microbial Stabilization filter cartridges are made from monomers and additives consistent with Annex I of European Regulation (EU) number 10/2011 and its amendments relating to plastic materials and articles intended to come in contact with foodstuffs (excluding seals).

Migration testing of cartridges employing the same materials of construction as the ‘W’ code Imperium Microbial Stabilization filter, has been performed, and met migration criteria after flushing and in flow conditions.

OML tested as 10” IMPCMSBDW In:-

Simulant B (3% acetic acid) for 2 hours at reflux,

Plus Simulant D1 (ethanol 50%) for 2 days at 60 °C.

- Our supplier states that the Silicone elastomeric seal material used conforms to BfR recommendation XV.
- Our supplier states that the Silicone elastomeric seal material used conforms to Arrete recommendation 25 Nov 1992.

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.

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 section 177.1520 (Olefin polymers)
- Polyethersulfone resin to 21 CFR section 177.2440 (Polyethersulfone resins)
- Silicone Elastomeric seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils)

In addition, the Imperium Microbial Stabilization filter employs a copolymer of polyethylene glycol dimethacrylate, trimethylol methacrylate and 2-hydroxyethyl methacrylate. Filters employing this chemistry in a membrane cartridge for the filtration of beer and wine, have been granted Food Contact Substance Notification FCN 001397, for use as repeat microbial filter intended to clarify beer and wine and FCN 001509, for use in filters for bottled water and for bottled water intended for use in preparation of infant formula.

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 Manufacturing (UK) Ltd., Ilfracombe, UK on behalf of Pall International Sàrl.

The Quality Management System at Pall Ilfracombe 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.

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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