

Declaration of Compliance with Regulation (EC) No 1935/2004

Product: PEPLYN HA



This filter meets the requirements for food contact, as detailed in European Regulation (EC) Number 1935/2004, in that our suppliers' or subsequent third party testing has confirmed the materials of construction meet regulatory and legislative requirements and guidelines, as outlined below:

The polymeric materials of construction of these filters are made from monomers and additives listed in EU Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

Migration testing of these filters (excluding seals), according to 82/711/EEC and/or BS EN 1186-15, has shown to meet overall requirements for food contact use as detailed in European Regulation 1935/2004/EC after flushing and in flow conditions

2023/2006/EC: Good Manufacturing Practices; Parker domnick hunter compliance is assured via independently accredited certification to PS9001, which is an application guide issued by the Pharmaceutical Quality Group of the Chartered Institute of Quality Assurance. PS9001 is ISO9001 integrated with GMP requirements based on assessed intermediate level of risk. The relevant ISO9001, ISO13485 and PS9001 certificates are available on request. No additional sources of material are introduced as part of the manufacturing and component assembly process at Parker domnick hunter.

This product is manufactured using the following components. Cross references to relevant TML and SML testing are stated

Part Reference	Brief Description	Report Number/s
019500508	Injection molded end caps	EA080110/13
019500508	Injection molded sleeve & core	EA080110/13
049501261	Extruded net support	10EA0904A, 11EA0304B
049501352	Melt blow filtration media	11EA0411, 11EA0412

Allowed Food Contact

This product is designed to be suitable contact, for the purposes of filtration, with the following food types;

- Aqueous Foods (i.e. aqueous foods having pH > 4.5)
- Acidic foods (i.e. aqueous foods having pH ≤ 4.5)
- Alcoholic foods
- Fatty foods

Surface Area to Volume Ratios

Total volumes of food stuff contacting the filter in its life time will be application dependent but are typically of the magnitude of 100,000s of lites per filter. Filter surface area is specified as 0.79m².

$$SA:V = 0.79m^2/100m^3 = 7.9 \times 10^{-3}$$

Product Contact Time and Temperatures

During use this product is calculated to be in contact with the filtrate for < 1 seconds. Filter specification for maximum continuous operating temperature is 70°C

$$\text{Filter area} = 0.79m^2$$

$$\text{Rated flow for product} = 10l/min, \text{ or } 1.66 \times 10^{-4} m^3/sec$$

$$\text{Filter pack depth} = 20mm \text{ or } 0.02m$$

$$\text{Velocity} = \text{flow rate} / \text{surface area, or } (1.66 \times 10^{-4} m^3/sec) / (0.79m^2) = 2.10 \times 10^{-4} m/sec$$

$$\text{Contact time} = \text{Velocity} / \text{Filter pack depth, or } (2.10 \times 10^{-4} m/sec) / 0.02m = 0.0105 \text{ Seconds}$$

Signed:

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