

# Emflon™ HTPFR

## FILTER CARTRIDGES

Emflon™ HTPFR filter cartridges are durable hot air filters for easy water intrusion testing. The cartridges are specifically designed for the sterile filtration of air, gas and vent service in critical, high-temperature and ozonated-water venting applications. They can also be considered for use in oxygen-enriched air applications in the biopharmaceutical and biotechnology industries. High-temperature applications include autoclave, fermentation inlet air, aseptic packaging/blow-fill-seal and hot water for injection (WFI) tank vents. These filters incorporate a double-layer (0.2 µm) of inherently hydrophobic, Cytiva-manufactured PTFE membrane. The polypropylene hardware is specially formulated with protective anti-oxidants and the filter's support and drainage layers are made of polyphenylene sulfide (PPS) polymer. Oxidation-resistant filter components allow extended use in air/vent service up to 100°C and for shorter periods up to 120°C.

## Features and benefits

Features	Benefits
Designed for water intrusion test (WIT)	No alcohol required
Oxidation-resistant materials of construction	Long service life in hot air and vent applications; also suitable for oxygen-enriched fermenter applications (1)
Proprietary, Cytiva-manufactured polytetrafluoroethylene (PTFE) membrane	Hydrophobic membrane, subject to rigorous membrane and quality controls; secure supply source
Validated with <i>B. diminuta</i> at >10 <sup>7</sup> cfu/cm <sup>2</sup>	Provides sterile air/gas under wet and dry conditions, meets cGMP sterilizing-grade filter requirements
Fully validated under stringent microbial, phage and particulate challenge tests	Improves microbial safety; mitigates virus contamination risk
Designed for multi-cycle autoclave and <i>in situ</i> steam	Robust construction offers enhanced steam resistance
High flow rates, low pressure drops	Allows smaller filtration systems, reducing installation and operational costs
Laser-etched part/serial number and 2D matrix code	Easily traceable; product information easily read or scanned with a barcode reader



Fig 1. Emflon HTPFR filter cartridges.

## Certified for pharmaceutical use

Emflon HTPFR filter cartridges are qualified for use in pharmaceutical GMP manufacturing. Each filter is supplied with a certificate of test confirming pharmaceutical industry requirements for fabrication integrity, effluent quality and biological safety testing. Our filters are manufactured in a controlled environment under a quality management system certified to ISO9001:2008. All HTPFR cartridges are forward flow integrity-tested in manufacturing, correlated to bacterial retention in liquids and bacteriophage (virus) retention in air, and are fully traceable by laser-marked lot and serial number. Filter lot samples are also tested for water intrusion.



**Fig 2.** Emflon HTPFR cartridge being scanned with a Palltronic® barcode reader and connected to a Palltronic Flowstar IV integrity test instrument.

Filter components meet requirements for biological reactivity *in vivo* under USP <88> for Class VI – 121°C plastics and *in vitro*, under USP <87> (elution test). This includes the systemic toxicity test, intracutaneous test, implantation test and the MEM elution cytotoxicity test. The filters are made from materials listed for food contact usage per Title 21 of the U.S. Code Of Federal Regulations (CFR) Parts 170-199.

## Effluent quality tests

- Meets with adequate safety margin the current limits under USP <788> particulate matter in Injections after flushing, with effluent counts determined microscopically.
- Non-fiber-releasing per title 21 of the U.S. Code Of Federal Regulations (CFR) parts 211.72 and 210.3(b)(6).
- Meets the current USP oxidizable substance requirement after flushing, under sterile water for injection, as determined by a potassium permanganate test.
- Meets internal specification for pH after flushing when tested in accordance with USP <791>.
- Meets internal specifications for pyrogens when an aliquot from a soak solution is tested using the limulus amoebocyte lysate (LAL) reagent in accordance with USP <85> bacterial endotoxins test.

## Technical specifications

### Materials of construction

Membrane	Proprietary, double-layer 0.2 µm hydrophobic polytetrafluoroethylene
Support and drainage layers	Polyphenylene sulfide
Core, cage, end caps and adapters	Polypropylene (high antioxidant formulation with encapsulated stainless steel reinforcing ring for dimensional stability during steam exposure)

### Maximum differential pressure <sup>(1)</sup>

Temperature	Forward direction	Reverse direction
Up to 40°C	5.4 bard (79 psid)	3.0 bard (43.5 psid)
Up to 90°C	3.4 bard (49 psid)	1.0 bard (14.5 psid)

### Autoclave / steaming <sup>(2)</sup>

Max. steaming conditions <sup>(3,4)</sup>	Pressure and temperature	Cumulative steaming time <sup>(3,4)</sup>
Forward	1.0 bard (14.5 psid) at 125°C	20 h (1 h cycles)
	0.3 bard (4.4 psid) at 142°C	100 h (1 h cycles)
Reverse	0.5 bard (7.3 psid) at 125°C	20 h (1 h cycles)

### Typical service life in continuous flowing air service <sup>(1,5)</sup>

Maximum temperature	Service life
100°C	12 months
110°C	6 months
120°C	2 months

### Effective filtration area <sup>(6)</sup>

127 mm (5 in.) cartridge	0.42 m <sup>2</sup> (4.52 ft <sup>2</sup> )
254 mm (10 in.) cartridge	0.84 m <sup>2</sup> (9.04 ft <sup>2</sup> )

<sup>(1)</sup> For differential pressure and temperature limits in applications with oxygen-enriched air, please refer to reference (1) or contact Cytiva.

<sup>(2)</sup> The steam life and service life data were determined by testing under controlled laboratory conditions up to the time indicated. Actual operating conditions may affect the filter cartridge's long-term resistance to steam sterilization and hot air service. Filter cartridges should be qualified for each process.

<sup>(3)</sup> Lab tests to establish multi-cycle resistance. Filters should be qualified in actual use. Contact us for recommended procedures.

<sup>(4)</sup> Excursion conditions only.

<sup>(5)</sup> Service life in intermittent air flow service, i.e. venting, may be significantly longer, depending on cumulative time in flowing air and temperature.

<sup>(6)</sup> Values are for one 254 mm (10 in.) filter cartridge and one 127 mm (5 in.) filter cartridge.

## Integrity test values <sup>(7)</sup>

Test	Solvent	Gas	Pressure	Limit 127 mm (5 in.) cartridge	Limit 254 mm (10 in.) cartridge
Forward flow	60:40 (v/v) isopropyl alcohol:water	Air	1040 mbar (15 psi)	Maximum 8 mL/min	Maximum 16 mL/min
Water intrusion	Water	Air	2500 mbar (36 psi)	Maximum 0.16 mL/min	Maximum 0.33 mL/min

AB05HTPFR air flow / differential pressure (housing losses subtracted)

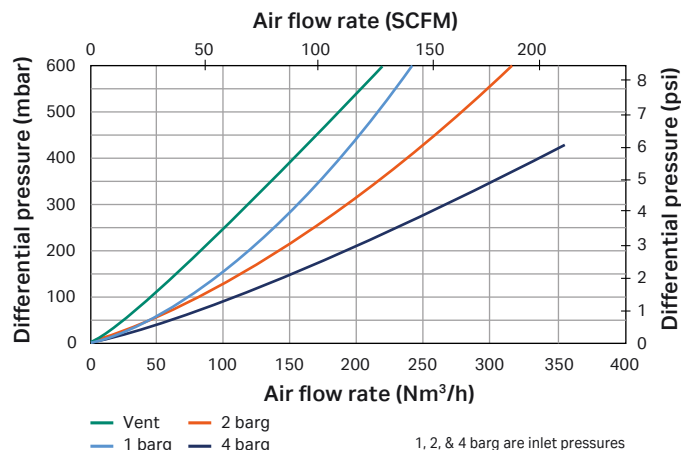


Fig 3. Typical air flow at 20°C for the 127 mm (5 in.) cartridge.

AB1HTPFR air flow / differential pressure (housing losses subtracted)

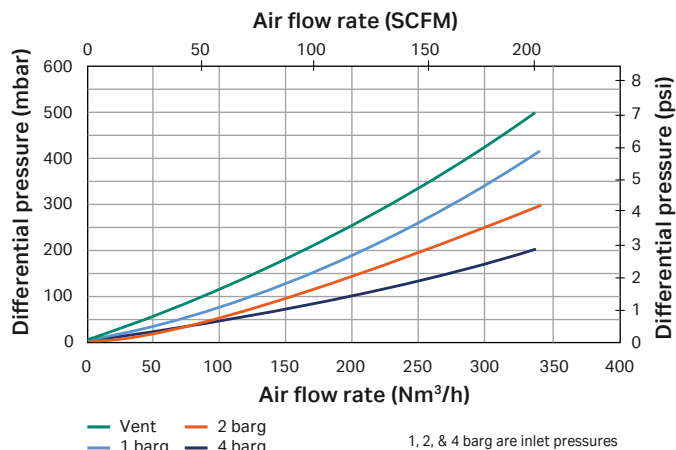


Fig 4. Typical air flow <sup>(8)</sup> at 20°C for the 254 mm (10 in.) cartridge.

## Ordering information <sup>(9)</sup>

Product	Length (nominal)	Product code
Emflon HTPFR filter cartridge, double 226 O-ring with bayonet lock, no fin, silicone seal	127 mm (5 in.)	AB05HTPFR2PVH4
Emflon HTPFR filter cartridge, double 226 O-ring with bayonet lock and finned cap, silicone seal	254 mm (10 in.)	AB1HTPFR7PVH4
Emflon HTPFR filter cartridge, double 226 O-ring with bayonet lock and finned cap, ethylene propylene seal	254 mm (10 in.)	AB1HTPFR7PVJ
Emflon HTPFR filter cartridge, double 226 O-ring with bayonet lock and finned cap, silicone seal	508 mm (20 in.)	AB2HTPFR7PVH4
Emflon HTPFR filter cartridge, double 226 O-ring with bayonet lock and finned cap, ethylene propylene seal	508 mm (20 in.)	AB2HTPFR7PVJ
Emflon HTPFR filter cartridge, double 226 O-ring with bayonet lock and finned cap, silicone seal	762 mm (30 in.)	AB3HTPFR7PVH4
Emflon HTPFR filter cartridge, double 226 O-ring with bayonet lock and finned cap, ethylene propylene seal	762 mm (30 in.)	AB3HTPFR7PVJ

<sup>(7)</sup> Values are for one 254 mm (10 in.) cartridge and one 127 mm (5 in.) cartridge at 20°C (68°F). Please contact Cytiva for multi-element integrity test values, different test gas or integrity test solvent.

<sup>(7)</sup> Values are for one 254 mm (10 in.) cartridge and one 127 mm (5 in.) cartridge at 20°C (68°F). Please contact Cytiva for multi-element integrity test values, different test gas or integrity test solvent.

<sup>(8)</sup> Typical initial clean medium differential pressure per 254 mm (10 in.) filter cartridge, air at 20°C. For multi-length cartridges, divide pressure drop by number of 254 mm (10 in.) filter cartridges. Contact us for assistance in sizing.

<sup>(9)</sup> This is a guide to the product code structure only. For availability of specific options, please contact Cytiva.

## Reference

1. Application note: Sterilizing filtration of enriched and pure gaseous oxygen employed in cell culture applications.

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