

Data Sheet

Solvex™

Solvent Filtration Cartridge Filters

RELIABLE API FILTRATION DESIGNED TO FIT YOUR NEEDS



Optimized filtration means meeting the changing requirements of your processes and the regulations that govern them. This is why Millipore offers you a choice. Solvex hydrophobic 0.22 µm solvent filtration products provide validated, robust, and cost-efficient solvent filtration. Millipore Solvex brand cartridge filters combine high-performance polytetrafluoroethylene (PTFE) membranes with a robust cartridge design to deliver validated, reliable sterile filtration and efficient particulate removal. A polymer with broad chemical and caustic compatibility, PTFE is ideal for use in the manufacture of active pharmaceutical ingredients containing methylene chloride, acetone, isopropyl alcohol, ethyl acetate and other organic solvents.

Benefits

- Ideal for sterile manufacture of active pharmaceutical ingredients (API)
- Suitable for filtration of a wide variety of organic solvents
- Robust construction and easy scale-up to meet changing process needs

Solvex filters meet your highest standard for sterility assurance, regulatory compliance and economy. With the quality you expect from a trusted supplier, Solvex brand solvent filters offer superior value through consistent and reliable performance that is guaranteed for up to 100 steam-in-place cycles. Solvex PTFE cartridge filters are available in 10-, 20-, and 30-inch sizes in code 7 O-ring adapters. Validation services and applications support are available through our AccessSM Services program.

RELIABILITY

Solvex cartridge filters promote a consistent, repeatable manufacturing process characterized by high-capacity, low extractables, and resistance to thermal and hydraulic stress. The proven performance of Millipore's filtration devices ensures uniform results every time.

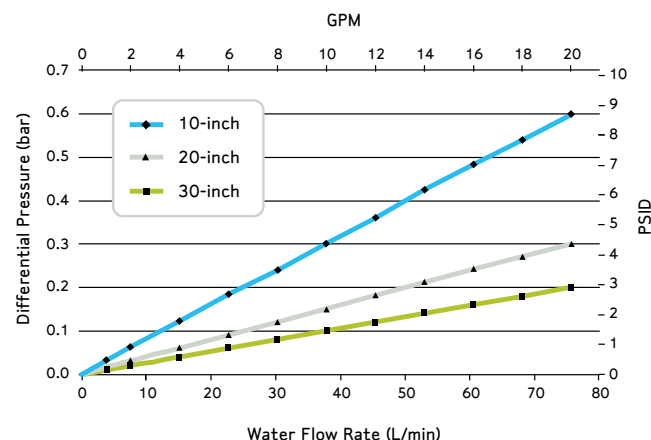
COMPLIANCE

Millipore cartridges are designed and thoroughly validated for product and process quality. Each lot of Solvex brand filters is verified during manufacture for flow rate and bacterial endotoxins and each cartridge is tested for integrity prior to release.

ECONOMY

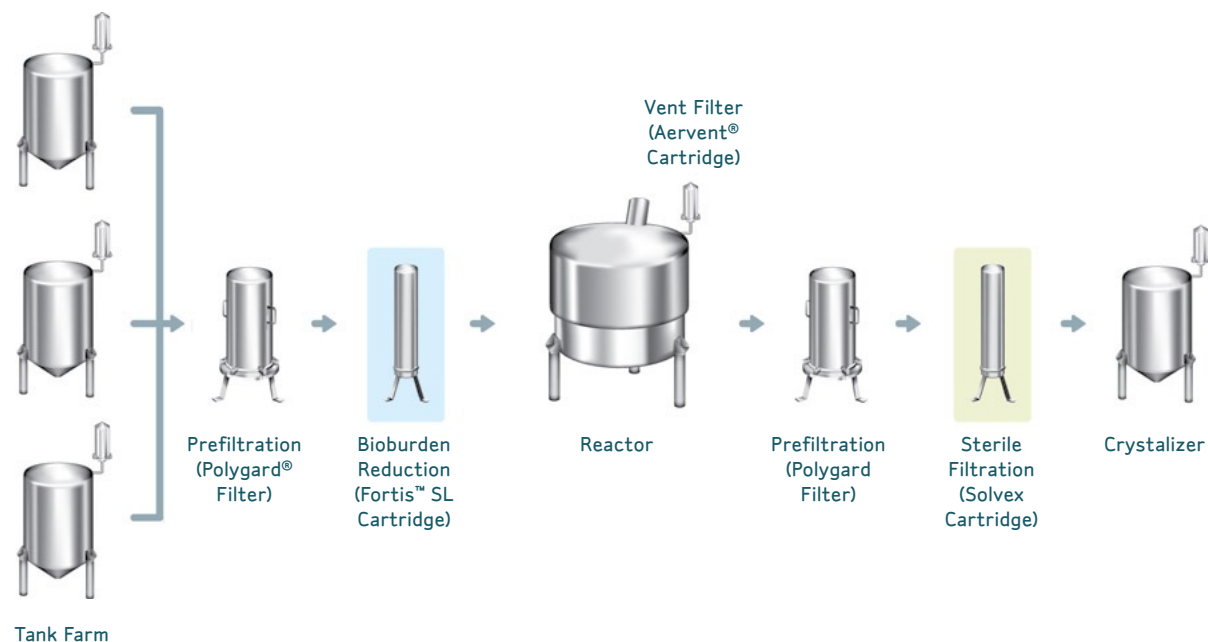
Solvex cartridge filters gives you the flexibility of reusing the filter multiple times, promoting an economical filtration process. Solvex cartridges can be autoclaved or steamed in place up to 100 times at temperatures of up to 135 °C.

Figure 1. Solvex Cartridges Water Flow Rate vs. Differential Pressure*



* Typical Values for H₂O.

Figure 2. Hydrophobic 0.22 µm Cartridge Filters in Antibiotic Production



Specifications

Per 10-inch Cartridge

Nominal Dimensions

Outside diameter	70 mm (2.8 in.)
Maximum length:	
10-inch cartridge	319 mm (12.6 in.)
20-inch cartridge	568 mm (22.0 in.)
30-inch cartridge	816 mm (32.1 in.)
Filtration Area	0.52 m ² (5.6 ft ²)

Materials of Construction

Filter media	PTFE membrane
Supports	Polypropylene
Structural components	Polypropylene
O-rings	EPDM

Maximum Differential Pressure

Forward:	
5.5 bar (80 psid) at ambient temperature,	
1.8 bar (25 psid) at 80 °C	
Reverse:	
4.1 bar (60 psid) at ambient temperature,	

Diffusion @ 23 °C

Through a 70/30 IPA/water wet membrane room at 965 mbar (14 psig) nitrogen:	
≤24 cc/min per 10-inch cartridge	

Bubble Point @ 23 °C

≥1310 mbar (19 psig) in a 70/30 IPA/water wet membrane using nitrogen	
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Gravimetric Extractables

After autoclaving and a 24 hour soak in 70/30 IPA water at controlled room temperature:	
≤35 mg	

Bacterial Endotoxin

Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.	
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Bacterial Retention

Samples were quantitatively retentive of a minimum <i>Brevundimonas diminuta</i> challenge concentration of 1 x 10 ⁷ CFU/cm ² using ASTM® F838 methodology.	
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Sterilization

May be steam sterilized 50 times (forward) and 50 times (reverse) for 30 minutes at 135 °C	
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Good Manufacturing Practices

These products are manufactured in a Millipore facility which adheres to FDA Good Manufacturing Practices.	
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Non-Fiber Releasing

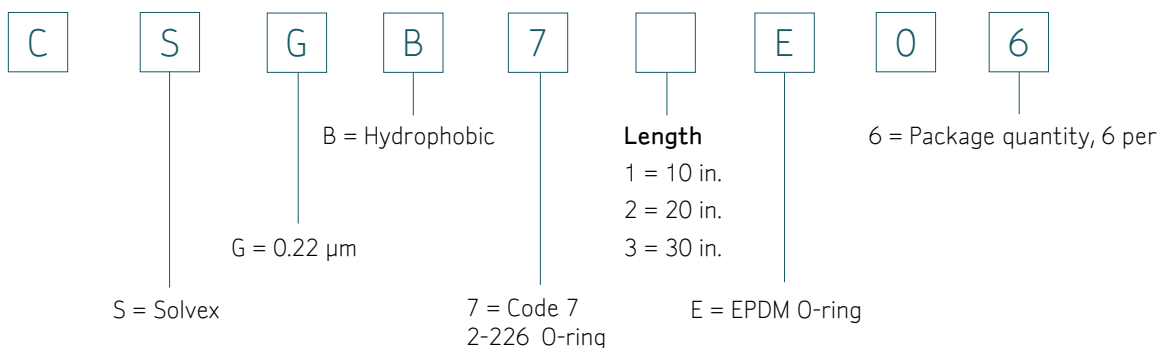
PTFE membrane meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).	
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Component Material Toxicity

Component materials were tested and meet the criteria of USP <88> Reactivity Tests for Class VI Plastics.	
Solvex filters are non-toxic per the USP <88> Safety Test.	

ORDERING INFORMATION

Solvex PTFE 0.2 µm Filter Cartridge for Solvent Filtration



TO PLACE AN ORDER OR RECEIVE TECHNICAL ASSISTANCE

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