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# Product Datasheet

# Sartolon

# Sterilizing-Grade Filter Elements

- Sterile filtration of solvents and oily formulations
- Unique hydrophilic nylon membrane with broad chemical compatibility
- Heterogeneous double layer design provides outstanding throughput and exceptional flow rates



# Perfectly Suited for Filtration of Solvents

Featuring a unique hydrophilic nylon (polyamide) membrane, Sartolon filters offer mechanical strength and broad chemical compatibility. They are the ideal choice for sterile filtration of solvents and oily formulations where chemical stability is needed.

# **Exceptional Filtration Performance**

In addition to its wide range of applications, Sartolon filters provide outstanding total throughput and flow rates due to their heterogeneous double-nylon layer. The enhanced filtration performance guarantees process efficiency, reduces filtration costs and leads to short filtration cycles.

# Scalability

Sartolon filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale. Membrane areas from 0.2 to 1.8 m<sup>2</sup> per filter element guarantee a high degree of flexibility and economic filter sizing.

# Applications

- Solvents & Oily Formulations
- Antibiotics
- Large Volume Parenterals
- Bulk Pharmaceutical Chemicals
- ADCs

## Services

Sartorius Confidence® Validation Services is the perfect complement to Sartolon.

## Our services provide

- Extractables and leachables services
- Microbiological testing
- Physicochemical testing

in compliance with regulatory requirements. Our local teams of validation experts support you with our tailored and consultative approach to determine the most costeffective solution and give you the confidence you need to succeed.

# Technical Data

Available Sizes	Filtration Area	Max. Diffusion at 2.5 bar   36 psi [ml/min]	Min. Bubble Point [bar psi]
Cartridges   Max	kicaps®		
Size 1	0.6 m²   6.5 ft²	13	3.0 43.5
Size 2	1.2 m²   12.9 ft²	26	3.0 43.5
Size 3	1.8 m²   19.4 ft²	39	3.0   43.5
Size 4 (only cartridge)	2.4 m <sup>2</sup>  25.9 ft <sup>2</sup>	52	3.0 43.5
Mini Cartridge	Midicaps®		
Size 9	0.2 m <sup>2</sup>   2.2 ft <sup>2</sup>	4	3.0   43.5

## Max. Allowable Differential Pressure

**Cartridges | Mini Cartridges** 5 bar | 72.5 psi at 20°C 2 bar | 29 psi at 80°C

#### Maxicaps<sup>®</sup> | Midicaps<sup>®</sup>

5 bar | 72.5 psi at 20°C 3 bar | 43.5 psi at 50°C

### Max. Allowable Back Pressure

2 bar | 29 psi at 20°C (for all elements)

### Materials

Prefilter Membrane Nylon (Polyamide), reinforced with PET fleece	
<b>Endfilter Membrane</b> Nylon (Polyamide)	
Support Fleece Polypropylene	
Core Polypropylene	
End Caps Polypropylene	
O-Rings Silicone (optional EPDM)	

### Pore Size Combination

0.45 µm + 0.2 µm

## **Regulatory Compliance**

- Each individual element is tested for integrity by Bubble Point and Diffusion test
- Fully validated as sterilizing grade filters according to ASTM current F-838 guidelines
- Designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System
- Meet or exceed the requirements for WFI quality standards set by the current USP
- Non-pyrogenic according to USP Bacterial Endotoxins
- Pass USP Plastic Class VI Test
- Non-fiber releasing according to 21 CFR

### Sterilization

#### Cartridges | Mini Cartridges

 In-Line Steam Sterilization Max. 134 °C, 0.3 bar, 20 min.
Min. 25 Sterilization Cycles

#### or

- Autoclaving
- Max. 134°C, 2 bar, 30 min Min. 25 Sterilization Cycles

#### Maxicaps<sup>®</sup> | Midicaps<sup>®</sup>

 Autoclaving Max. 134°C, 2 bar, 30 min Min. 25 Sterilization Cycles

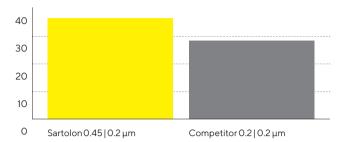
#### **Technical References**

Validation Guide	SPK5716-e
Extractables Guide	SPK5729-e

#### Performance

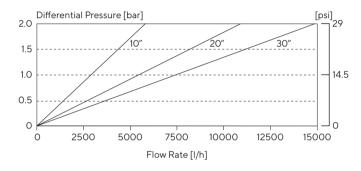
#### Total Throughput Comparison

Total Throughput at 95% blockage [kg]



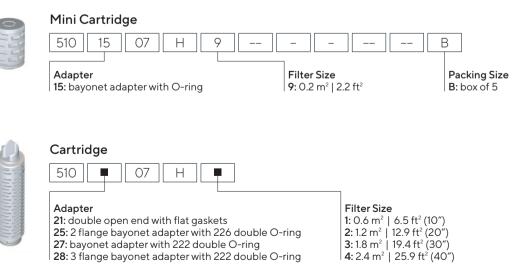
#### 10″ Cartridge

#### Water Flow Rates Sartolon Maxicaps®

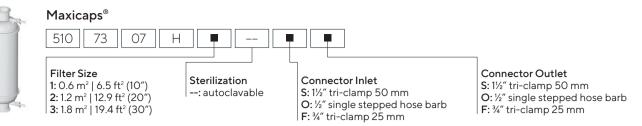


Standardized at 20°C

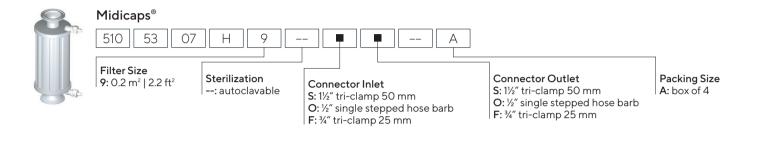
# Ordering Information



(Standard with silicone O-ring, optionally with EPDM O-ring. Example 5102507H1---E)



(Optionally with vent valve design for connection to integrity tester. Example: 5107307H1--SSIT)



Check the availability of your desired configuration with your Sartorius sales representative or online at www.sartorius.com

#### Germany

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