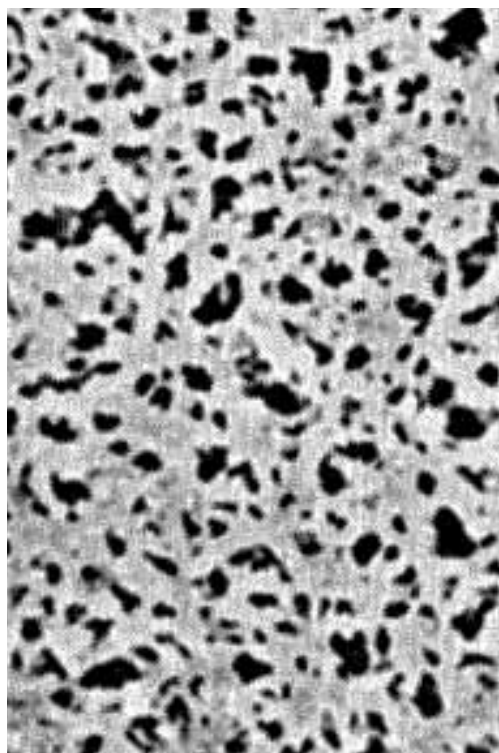




sartorius stedim
biotech

Microfilters Product Overview



По вопросам продаж и поддержки обращайтесь:

Астана+7(7172)727-132, Волгоград(844)278-03-48, Воронеж(473)204-51-73, Екатеринбург(343)384-55-89,
Казань(843)206-01-48, Краснодар(861)203-40-90, Красноярск(391)204-63-61, Москва(495)268-04-70,
Нижний Новгород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,
Санкт-Петербург(812)309-46-40, Саратов(845)249-38-78, Уфа(347)229-48-12

sst@nt-rt.ru || sartorius.nt-rt.ru

Table of contents

1.	Introduction	4	4.	Test Methods and	
2.	Quality and its Assurance	5		Technical Information	38
2.1	Quality Assurance in Conformance with the Applicable Current Good Manufacturing Practices	5	4.1	Information on Sterilization	38
2.2	Quality Assurance	5	4.1.1	Autoclaving	38
2.3	Complete Traceability	5	4.1.2	Steam Sterilization	38
2.4	DIN EN ISO 9001 Certificates	5	4.1.3	Sterilization by Dry Heat	38
			4.1.4	Sterilization with ETO	38
			4.1.5	Sterilization by γ -Radiation	38
3.	Membrane Types	6	4.1.6	Sterilization by Chemical Disinfection	38
3.1	Cellulose Nitrate Membranes		4.1.7	Ready-to-use Filters (Pre-Sterilized)	38
	- Type 11303 11302 11342 11301	6	4.2	Test methods	
	- Type 11403 13903	7	4.2.1	Bubble Point	38
	- Type 11404	8	4.2.2	Thickness	38
	- Type 13004	9	4.2.3	Flow rate with Water Ethanol	38
	- Type 11305 11304	10	4.2.4	Extractables with Water Ethanol	38
	- Type 11405 13905 13005	11	4.2.5	Burst Pressure	38
	- Type 114H6 139H6	12	4.2.6	Air Flow	39
	- Type 11306	13	4.2.7	Protein Binding	39
	- Type 11406 13906	14	4.2.8	Bacteria Challenge Test	39
	- Type 13106	15	4.2.9	Growth Promotion Test	39
	- Type 13006	16	4.2.10	Sterility test	39
	- Type 13806	17	4.3	Chemical Compatibility	
	- Type 11407	18	4.3.1	Test Method	39
	- Type 13107	19	4.3.2	Results on Chemical Compatibility	40
3.2	Cellulose Acetate Membranes		4.4	Test Methodes According to USP	
	- Type 12342	20	4.4.1	Particle Content in the Filtrate	41
	- Type 12303	21	4.4.2	Extractable Substances	41
	- Type 11104	22	4.4.2.1	Test Methods	41
	- Type 11105	23			
	- Type 11106	24	5.	Validation Guide	42
	- Type 11107	25	5.1	Bacteria Challenge test	42
	- Type 13507 and 13506	26	5.1.1	Correlation Bubblepoint with Sartocheck to BC test	42
3.3	PTFE-Membranes		5.1.1.1	Test method	42
	- Type 11806	27	5.1.1.2	Results	43
	- Type 11807	28	5.1.2	Correlation Bubble Point accoring DIN 58355 to BC test	44
3.4	Polyethersulfone Membranes		5.1.2.1	Test method	44
	- Type 15406	29	5.1.2.2	Results	44
	- Type 15407MI	30	5.2	Testing According to USP	45
	- Type 15458	31	5.2.1	Particle content in the filtrate	45
3.5	Regenerated Cellulose Membranes		5.2.1.1	Test Methods	45
	- Type 18406	32	5.2.1.2	Results	45
	- Type 18407	33	5.2.2	Extractable Substances	46
3.6	Polycarbonate Membranes		5.2.2.1	Test method	46
	- Type 23006	34	5.2.2.2	Results	46
	- Type 23007	35	5.2.3	Content of Endotoxins	47
3.7	Polyamide Membranes		5.2.3.1	Test method	47
	- Type 25006	36	5.2.3.2	Results	47
	- Type 25007	37	5.2.4	Biological tests (Plastic class tests)	47
			5.2.4.1	Test method	47
			5.2.4.2	Results	47
			5.2.5	Cytotoxicity test	47
			5.2.5.1	Test method	47
			5.2.5.2	Results	47
			6.	Application Matrix	48

1. Introduction

Sartorius Stedim Biotech started the first ever industrial production of microfilter membranes in 1929. Since then our manufacturing technology has been continuously improved. Today microfilter membranes are cast, slit and packaged at our new plant on state-of-the-art casting machines, in compliance with ISO 9001 requirements.

A tradition for quality combined with the highest industrial standards and our in-house applications know-how enable us to produce microfilter membranes with outstanding performance, quality and consistency.



2. Quality and its Assurance

2.1 Quality Assurance in Conformance with the Applicable Current Good Manufacturing Practices

Consistently, high quality of Sartorius Stedim Biotech membrane filters is assured by careful selection of the raw materials, well planned and validated production technologies and an efficient quality assurance. The test procedures used are based both on external standards such as USP, EP, DIN and ASTM, and on special in-house methods which are the result of Sartorius Stedim Biotech's years of technical experience in the field of membrane casting.

2.2 Quality Assurance

All materials are selected carefully in accordance with current regulations and recommendations, such as the FDA's CFR, applicable Good Manufacturing Practices and in-house guidelines. The specifications are based on national and international standards as well as those developed by our Research and Development Department. Documentation starts with the inspection of incoming raw materials for manufacturing. All membranes must pass extensive tests according to protocol before being released. Requirements according to applicable current Good Manufacturing Practices (clean room conditions, gowning and employee hygiene, etc.) ensure optimal quality control in standard operating procedures for production.

2.3 Complete Traceability

Pore size, type and lot number are printed on the labels of the protective plastic case and of the paper box which covers the plastic case. A traceable lot number allows convenient retrieval of all data compiled on the materials, production steps and QC tests.

Part Number Overview

Material

111 => Cellulose acetate (CA)
113 => Cellulose nitrate (CN)
114 => Cellulose, black grid
123 => Cellulose acetate (CA)
139 => Cellulose, green grid
138 => Cellulose nitrate, green grid
130 => Cellulose nitrate, black grid
131 => Cellulose nitrate, hydrophobic edge
135 => Cellulose acetate, hydrophobic edge
118 => Polytetrafluoroethylene (PTFE)
154 => Polyether sulfone (PES)
184 => Regenerated cellulose, reinforced (RC)
250 => Polyamide (PA)
230 => Polycarbonate track-etch membrane (PC)

Nominal Pore Size

01 => 8 µm
42 => 5 µm
02 => 3 µm
03 => 1.2 µm
04 => 0.8 µm
05 => 0.65 µm
06 => 0.45 µm
H6 => High flow
07 => 0.2 µm
58 => 0.1 µm

Diameter

293 mm
142 mm
100 mm
90 mm
50 mm
47 mm
37 mm
35 mm
30 mm
25 mm
20 mm
13 mm

Pack Size

G => 25
K => 50
N => 100
R => 1000
AC => Individual sterile packed
SCM => pleated version without protective disc
ACN => pack of 100 individual sterile packed
ACR => pack of 1000 individual sterile packed
HCN => with 6 mm pink colored edge
MIN => specific PES material 100 filter/unit

For Example:

111 07--47-----N

111 => Cellulose acetate
07 => 0.2 µm
47 => 47 mm diameter
N => 100 membranes per unit

2.4 DIN EN ISO 9001 Certificates

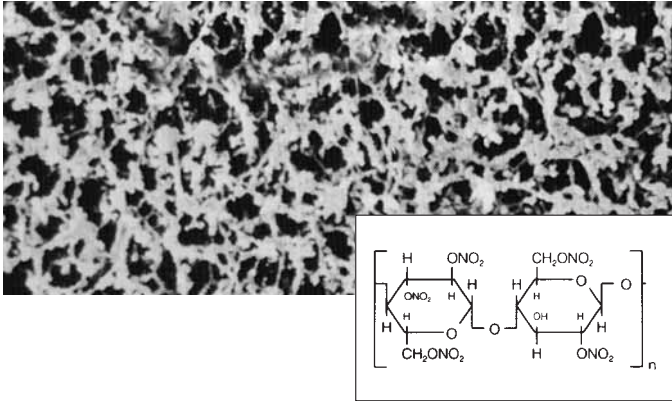
Sartorius Stedim Biotech implemented Quality Management Systems to assure consistent high quality of Membrane Filters, Ultra Filters, Filter Cartridges and Disposables.

Exemplary Quality Systems Certificates:

- Global Quality Systems Certificates | Quality Certificates (ISO 9001:2000)
- Global Quality Systems Certificates | Quality Certificates for Medical Devices (ISO 13485:2003 and directive 93/42/EEC)

The complete Quality Systems Certificates are continuously updated and can be downloaded on our website: www.sartorius-stedim.com/qm-certificates

3. Membrane Types | 3.1 Cellulose Nitrate Membranes Type 11303 | 11302 | 11342 | 11301; white, large pore sizes



Order Numbers

13 mm diameter:
11342-013N, pack of 100
11342-013N, pack of 100
11301-013 N, pack of 100

25 mm diameter:
11303-025N, pack of 100
11302-025N, pack of 100
11342-025N, pack of 100
11301-025N, pack of 100

37 mm diameter:
11301-037 N, pack of 100

47 mm diameter:
11303-047N, pack of 100
11303-047ACN, pack of 100
individual sterile packed
11302-047N, pack of 100
11302-047ACN, pack of 100
individual sterile packed
11342-047N, pack of 100
13001-047N, pack of 100
11301-047ACN, pack of 100
individual sterile packed

50 mm diameter:
11303-050N, pack of 100
11303-050ACN, pack of 100
individual sterile packed
11302-050N, pack of 100
11302-050ACN, pack of 100
individual sterile packed
11342-050N, pack of 100
11301-050N, pack of 100
11301-050ACN, pack of 100
individual sterile packed

80 mm diameter:
11301-080ALN, pack of 100
not individual sterile packed

90 mm diameter:
11303-090N, pack of 100
11342-090N, pack of 100

142 mm diameter:
11303-142G, pack of 25
11302-142G, pack of 25
11342-142G, pack of 25
11342-142N, pack of 100
11301-142G, pack of 25

293 mm diameter:
11303-293G, pack of 25
11342-293G, pack of 25
11301-293G, pack of 25

Description

Cellulose nitrate membrane filters with larger pore sizes are indicated for many purposes where a membrane with a high non-specific adsorption is suitable but a small pore size is not required.

Color

White, no grid.

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic

Pore Size (Nominal)

11303 1.2 μm
11302 3 μm
11342 5 μm
11301 8 μm

Structure

Symmetric

Applications and Features

Typical Applications

Cell retention, diagnostic kits, particle retention, clear filtration etc.

Special Features

- High flow rate
- High non-specific adsorption

Technical Advantages

Typical Performance

Adsorption, Non-specific

The non-specific adsorption decreases with increasing pore size, see example of γ -globulin

Bubble Point with Water (DIN 58355)

11303 1.0 bar | \sim 14.5 psi
11302 0.5 bar | \sim 7.2 psi
11342 0.5 bar | \sim 7.2 psi
11301 0.3 bar | \sim 4.3 psi

Burst Pressure

for 11342 0.2 bar | \sim 2.9 psi

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents.

Extractables with Water

< 1%

Flow Rate for Air [L/m²/s 200 Pa] according to*

11303 7.5 l/min
11302 13.5 l/min
11342 24 l/min
11301 41 l/min

corresponding water flow rates

(ml/min at $\Delta p = 1$ bar | \sim 14.5 psi) approx.:

11303 200
11302 430
11342 570
11301 750

Sterilization Methods

Autoclaving at 121°C, ETO sterilization, γ -irradiation (25 kGy)

Thermal Resistance

130°C max.

Thickness (DIN 53105)

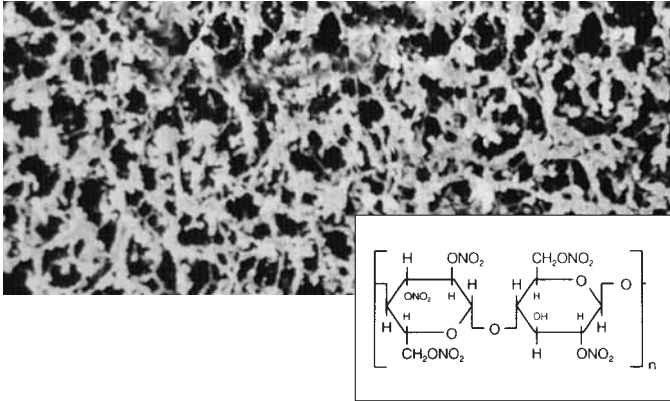
Approx. 130 μm

Sterility (AC)

Zero growth

* ASTM D737
DIN 53'887
ISO 9'237

3.1 Cellulose Nitrate Membranes Type 11403 | 13903; White, Black or Green Grid, 1.2 µm



Order Numbers

25 mm diameter:
11403-025N, pack of 100

47 mm diameter:
11403-047N, pack of 100
11403-047ACN, pack of 100
individual sterile packed
11403-047R, pack of 1000
11403-047ACR, pack of 1000
individual sterile packed
13903-047ACN, pack of 100
individual sterile packed

50 mm diameter:
11403-050N, pack of 100
11403-050ACN, pack of 100
individual sterile packed
11403-050ACR, pack of 1000
individual sterile packed

Description

Gridded cellulose nitrate membranes are the optimal, and most commonly used filters for microbiological testing of water, beverages, foods, pharmaceuticals, cosmetics and many other similar products.

Color

11403 white with black grid
13903 white with green grid

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic

Pore Size (nominal)

1.2 µm

Structure

Symmetric

Applications and Features

Typical Applications

Microbiological examination of soft drinks, fruit juices and other products that contain particles (like fruit pulp) and are therefore hard to filter.

Special Features

- high flow rate
- good growth of yeasts and molds

Technical Advantages

- Easier filtration and larger volumes possible for samples that contain particles or have a high viscosity.

Typical Performance

Adsorption, Non-specific

The non-specific adsorption decreases with increasing pore size, see example for γ -globulin.

Bubble Point with Water (DIN 58355)

11403 1.0 bar | ~ 15 psi
13903 1.0 bar | ~ 15 psi

Burst Pressure

0.2 bar | ~ 2.9 psi

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents.

Extractables with Water

< 1%

Flow Rate for Air [L/m²/s 200 Pa]

according to*

11403 7.5 l/min

13903 7.5 l/min

corresponding water flow rate:

approx. 320 ml/min at $\Delta p = 1 \text{ bar}$ | ~ 14.5 psi

Sterilization Methods

Autoclaving at 121°C, ETO sterilization, γ -irradiation (25 kGy)

Thermal Resistance

130°C max.

Thickness (DIN 53105)

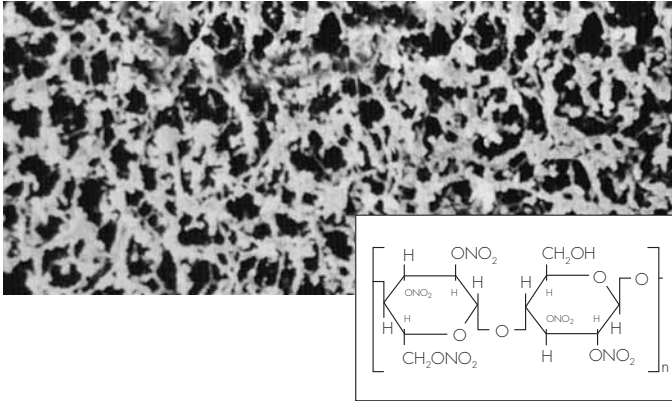
Approx. 130 µm

Sterility (AC)

Zero growth

* ASTM D737
DIN 53'887
ISO 9'237

3.1 Cellulose Nitrate Membranes Type 11404; White, Black Grid, 0.8 µm



Order Numbers

25 mm diameter:
11404-025N, pack of 100

37 mm diameter:
11404-037N, pack of 100

47 mm diameter:
11404-047N, pack of 100
11404-047ACN, pack of 100
individual sterile packed
11404-047ACR, pack of 1000
individual sterile packed

50 mm diameter:
11404-050N, pack of 100
11404-050ACN, pack of 100
individual sterile packed

Description

Gridded cellulose nitrate membranes are the optimal, and most commonly used filters for microbiological testing of water, beverages, foods, pharmaceuticals, cosmetics and many other similar products.

Color

White, black grid.

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic

Pore Size (nominal)

0.8 µm

Structure

Symmetric

Applications and Features

Typical Applications

Microbiological examination of hard-to-filter products and applications where a higher flow rate is required. Microbiological testing of airborne bacteria.

Special Features

– Excellent culture medium

Technical Advantages

- Grid does not inhibit microbial growth.
- The high flow rate allows fast filtration and is better for hard-to-filter products.
- Larger pore size promotes growth of microorganisms like Alicyclobacillus and some yeasts and molds.
- Can be used for airborne microbes at places with high air humidity.

Typical Performance

Adsorption, Non-specific

γ-globulin, approx. 80 µg/cm²

Bubble Point with Water (DIN 58355)

1.7 bar | ~ 25 psi

Burst Pressure

0.2 bar | ~ 2.9 psi

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents

Extractables with Water

< 1%

Flow Rate for Air [L/m²/s 200 Pa] according to*

5.2

corresponding water flow rate:

approx. 200 ml/min at Δp = 1 bar | ~ 14.5 psi

Sterilization Methods

Autoclaving at 121°C, ETO sterilization, γ-irradiation (25 kGy)

Thermal Resistance

130°C max.

Thickness (DIN 53105)

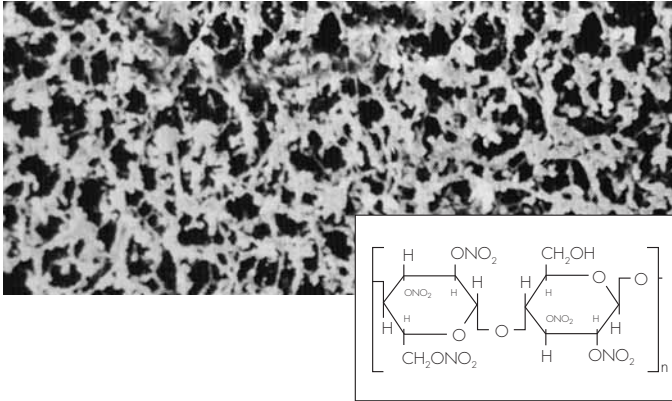
Approx. 130 µm

Sterility (AC)

Zero growth

* ASTM D737
DIN 53'887
ISO 9'237

3.1 Cellulose Nitrate Membranes Type 13004; Black, White Grid, 0.8 µm



Order Numbers

25 mm diameter:
13004-025N, pack of 100

37 mm diameter:
13004-037 N, pack of 100

47 mm diameter:
13004-047N, pack of 100
13004-047ACN, pack of 100
individual sterile packed
13004-047ACR, pack of 1000
individual sterile packed
13004-050N, pack of 100
13004-050ACN, pack of 100
individual sterile packed

80 mm diameter:
13004-080N, pack of 100
13004-080ALN, pack of 100
not individual sterile packed
Microsart dispenser filters

47 mm diameter:
13004Z-047SCM, pack of 300
pleated without protective disc

50 mm diameter:
13004Z-050SCM, pack of 300
pleated without protective disc

Description

Gridded cellulose nitrate membranes are the optimal, and most commonly used filters for microbiological testing of water, beverages, foods, pharmaceuticals, cosmetics and many other similar products.

Color

Grey (black when wetted), white grid.

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic

Pore Size (nominal)

0.8 µm

Structure

Symmetric

Applications and Features

Typical Applications

Microbiological testing of beverages, yeasts and molds. For testing airborne yeasts and molds at places high humidities.

Special Features

- Excellent growth medium
- High flow rate

Technical Advantages

- Grid does not inhibit microbial growth.
- Good recovery rate for yeasts and molds

Typical Performance

Adsorption, Non-specific

γ-globulin, approx. 70 µg/cm²

Bubble Point with Water (DIN 58355)

1.7 bar | ~ 25 psi

Burst Pressure

0.2 bar | ~ 2.9 psi

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents

Extractables with Water

< 3%

Flow Rate for Air [L/m²/s 200 Pa] according to*

5.2
corresponding water flow rate:
approx. 200 ml/min at Δp = 1 bar | ~ 14.5 psi

Sterilization Methods

Autoclaving at 121 °C, ETO sterilization, γ-irradiation (25 kGy)

Thermal Resistance

130 °C max.

Thickness (DIN 53105)

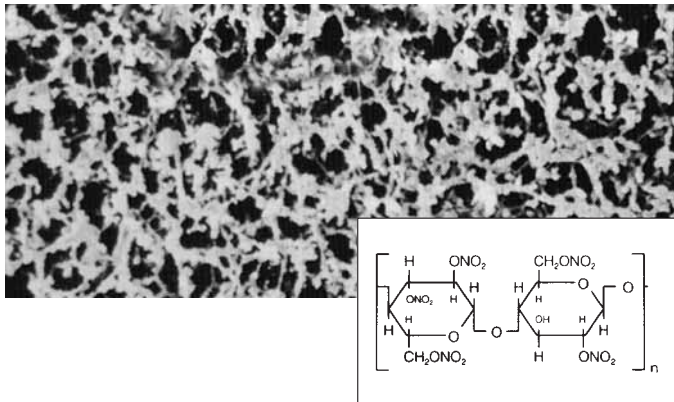
Approx. 140 µm

Sterility (AC)

Zero growth

* ASTM D737
DIN 53'887
ISO 9'237

3.1 Cellulose Nitrate Membranes Type 11305 | 11304; White, 0.65 µm | 0.8 µm



Description

Cellulose nitrate membrane filters with larger pore sizes are indicated for many applications where membranes with a high non-specific adsorption are suitable but small pore size is not required.

Color

White, no grid.

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic

Pore Size (Nominal)

11305 = 0.65 µm

11304 = 0.8 µm

Structure

Symmetric

Applications and Features

Typical Applications

Cell retention, sample pretreatment, particle retention, clarifying filtration etc.

Special Features

- Higher flow rate
- High non-specific adsorption

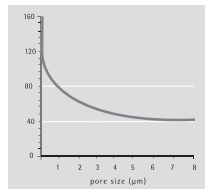
Technical Advantages

- Good retention rate for larger particles due to the high non-specific adsorption
- High flow rate

Typical Performance

Adsorption, Non-specific

The non-specific adsorption decreases with increasing pore size, see example for γ -globulin



γ -globulin,
approx. 125 µg/cm²

Bubble Point with Water (DIN 58355)

11305 2.0 bar | ~ 29 psi

11304 1.4 bar | ~ 20.3 psi

Burst Pressure

0.2 bar | ~ 2.9 psi

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents.

Extractables with Water

< 1%

Flow Rate for Water per cm² (DIN 58355)

11305 130 ml/min at $\Delta p = 1$ bar | ~ 15 psi

Flow Rate for Air [L/m²/s 200 Pa] according to*

corresponding water flow rate:
approx. 200 ml/min at $\Delta p = 1$ bar | ~ 14.5 psi

Sterilization Methods

Autoclaving at 121°C, ETO sterilization, γ -irradiation (25 kGy)

Thermal Resistance

130°C max.

Thickness (DIN 53105)

Approx. 130 µm

Sterility (AC)

Zero growth

Order Numbers

13 mm diameter:

11304-013N, pack of 100

20 mm diameter:

11304-020N, pack of 100

25 mm diameter:

11305-025N, pack of 100

11304-025N, pack of 100

37 mm diameter:

11308-037 N, pack of 100

47 mm diameter:

11305-047N, pack of 100

11305-047ACN, pack of 100

11304-047N, pack of 100

11304-047ACN, pack of 100

individual sterile packed

50 mm diameter:

11305-050N, pack of 100

11305-050ACN, pack of 100

individual sterile packed

11304-050N, pack of 100

11304-050ACN, pack of 100

individual sterile packed

90 mm diameter:

11304-090N, pack of 100

142 mm diameter:

11305-142G, pack of 25

11304-142G, pack of 25

11304-142N, pack of 100

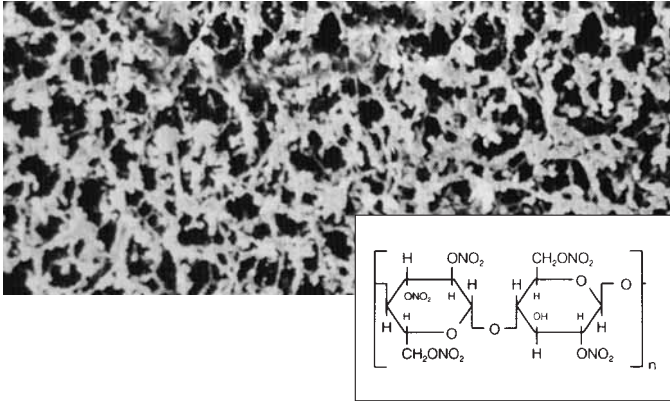
293 mm diameter:

11304-293G, pack of 25

11304-293N, pack of 100

* ASTM D737
DIN 53'887
ISO 9'237

3.1 Cellulose Nitrate Membranes Type 11405 | 13905 | 13005; Gridded, 0.65 µm



Description

Gridded cellulose nitrate membranes are the optimal, and most commonly used filters for microbiological testing of water, beverages, foods, pharmaceuticals, cosmetics and many other similar products.

Color

11405 White with black grid
13905 White with green grid
13005 Black with white grid (grey when dry)

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic

Pore Size (Nominal)

0.65 µm

Structure

Symmetric

Applications and Features

Typical Applications

Microbiological testing of water, pharmaceutical, foods, beverages and many other products where a higher flow rate is desired.

Special Features

- Excellent growth medium
- Higher flow rate
- Common for the detection of yeasts and molds

Technical Advantages

- Grid does not inhibit growth
- Absolute retention of yeasts and molds

Typical Performance

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents

Flow Rate for Water per cm² (DIN 58355)

130 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods

Autoclaving at 121 °C, ETO sterilization, γ-irradiation (25 kGy)

Thermal Resistance

130 °C max.

Thickness (DIN 53105)

115–145 µm

Growth Promotion Test (ISO 7704)

Bacterial recovery testing has shown that the grid lines do not enhance or inhibit the growth of microorganisms. Recovery rates of total and coliform bacteria indicate that there is no influence on bacterial growth and development due to chemical extractables.

pH of Filter Extract

< 8.3

Recovery Rate, Lot-released (DIN 7704)

≥ 90%

Sterility (AC)

Zero growth

Order Numbers

25 mm diameter:

11405-025N, pack of 100

47 mm diameter:

11405-047N, pack of 100

11405-047ACN, pack of 100

individual sterile packed

13905-047ACN, pack of 100

individual sterile packed

13005-47N, pack of 100

13005-07ACN, pack of 100

individual sterile packed

50 mm diameter:

11405-050N, pack of 100

11405-050ACN, pack of 100

individual sterile packed

13905-050ACN, pack of 100

individual sterile packed

13005-050N, pack of 100

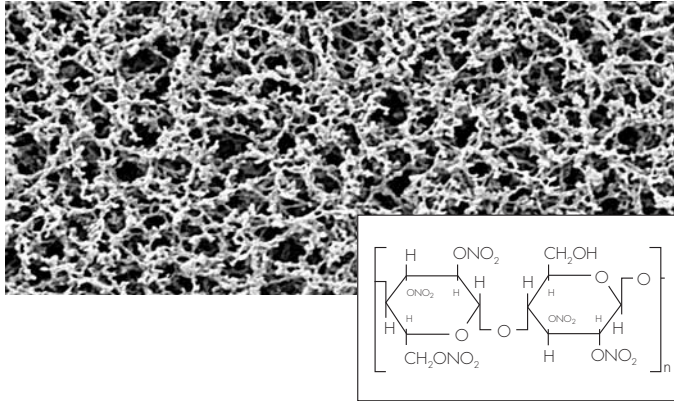
13005-050ACN, pack of 100

individual sterile packed

13005-050ACR, pack of 1000

individual sterile packed

3.1 Cellulose Nitrate Membranes Type 114H6 and 139H6; Gridded, 0.45 µm High Flow



Description

Gridded cellulose nitrate membranes are the optimal, and most commonly used filters for microbiological testing of water, beverages, foods, pharmaceuticals, cosmetics and many other similar products.

Color

114H6 White with black grid
139H6 White with green grid

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic

Pore Size (ISO 7704)

0.45 µm

Structure

Symmetric

Applications and Features

Typical Applications

Microbiological testing of water, pharmaceutical, foods, beverages and many other products for E. coli and coliforms bacteria.

Special Features

- Excellent growth medium
- Promotes perfect development of the typical colony morphology of bacteria on all culture media

Technical Advantages

- Does not inhibit growth at grid
- The modified pore structure gives a higher recovery rate for E. coli and coliforms than traditional membrane types 11406 and 13906

Typical Performance

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents.

Flow Rate for Water per cm² (DIN 58355)

100 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods

Autoclaving at 121°C, ETO sterilization, γ-irradiation (25 kGy)

Thermal Resistance

130°C max.

Thickness (DIN 53105)

115–145 µm

Growth Promotion Test (ISO 7704)

Bacterial recovery testing has shown that the grid lines do not enhance or inhibit the growth of microorganisms. Recovery rates of total and coliform bacteria indicate that there is no influence on bacterial growth and development due to chemical extractables.

pH of Filter Extract

< 8.3

Coliform Retention

100%

Recovery Rate, Lot-released (DIN 7704)

≥ 90%

Sterility (AC)

Zero growth

Order Numbers

47 mm diameter:

114H6-047ACN, pack of 100 individual sterile packed
114H6-047ACR, pack of 1000 individual sterile packed
139H6-047ACN, pack of 100 individual sterile packed
139H6-047ACR, pack of 100 individual sterile packed

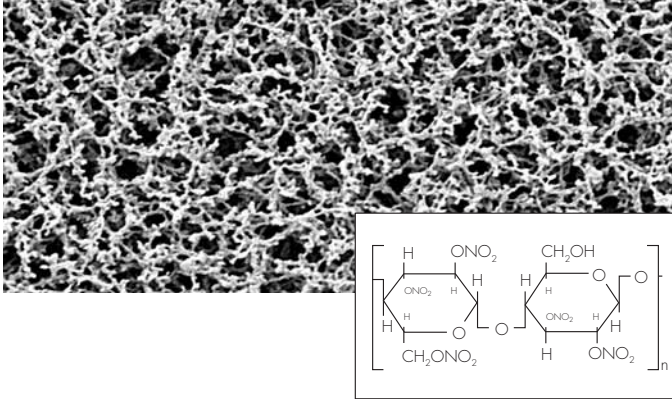
50 mm diameter:

114H6-050ACN, pack of 100 individual sterile packed
114H6-050ACR, pack of 1000 individual sterile packed
139H6-050ACN, pack of 100 Microsart dispenser filters

47 mm diameter:

114H6Z-047SCM, pack of 300 pleated without protective disc
13906Z-047SCM, pack of 300 pleated without protective disc

3.1 Cellulose Nitrate Membranes Type 11306; White, 0.45 µm



Description

Cellulose nitrate membranes have a very uniform pore structure and are available in a wide range of pore sizes.

Besides bacteria detection, the 0.45 µm membrane is used for clarifying filtration, particle collection or other analytical methods.

Color

White

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic

Pore Size (Nominal)

0.45 µm

Structure

Symmetric

Applications and Features

Typical Applications

Residue analysis, hybridity testing, liquid scintillation, ultracleaning of aqueous solutions.

Special Features

- Fine, uniform pore structure and high, non-specific adsorption.

Technical Advantages

- Effective removal of small particles on filter surfaces.
- Excellent for the filtration of water and other samples for clearing and reduction of the bioburden when sterile filtration is not required.

Typical Performance

Adsorption, non-specific

γ-globulin, approx. 125 µg/cm²

Bubble Point with Water (DIN 58355)

2.4 bar | ~ 35 psi

Burst Pressure

0.2 bar | ~ 2.9 psi

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents.

Extractables with Water

< 1%

Flow Rate for Water per cm² (DIN 58355)

70 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods

Autoclaving at 121 °C, ETO sterilization, γ-irradiation (25 kGy)

Thermal Resistance

130 °C max.

Thickness (DIN 53105)

Approx. 130 µm

Coliform Retention

100%

Sterility (AC)

Zero growth

Order Numbers

13 mm diameter:
11306-013N, pack of 100

20 mm diameter:
11306-020N, pack of 100

25 mm diameter:
11306-025N, pack of 100

30 mm diameter:
11306-030N, pack of 100

37 mm diameter:
11306-037N, pack of 100

47 mm diameter:
11306-047N, pack of 100
11306-047ACN, pack of 100
individual sterile packed

50 mm diameter:
11306-050N, pack of 100
11306-050ACN, pack of 100
individual sterile packed

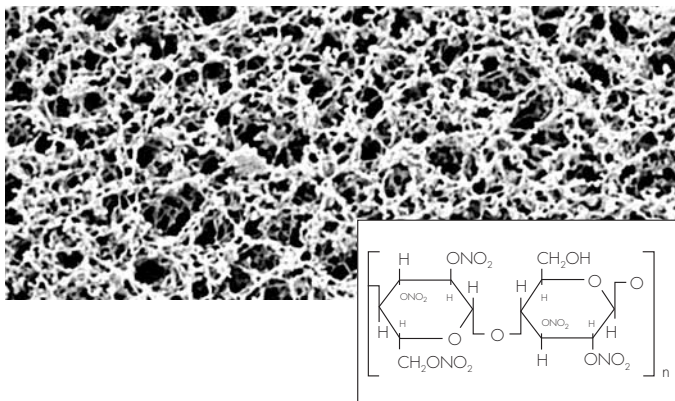
85 mm diameter:
11306-085N, pack of 100

90 mm diameter:
11306-090G, pack of 25
11306-090N, pack of 100

142 mm diameter:
11306-142G, pack of 25
11306-142N, pack of 100

293 mm diameter:
11306-293G, pack of 25
11606-293N, pack of 100

3.1 Cellulose Nitrate Membranes Type 11406|13906; White Grid, 0.45 µm



Description

Gridded cellulose nitrate membranes are the optimal, and most commonly used filters for microbiological testing of water, beverages, foods, pharmaceuticals, cosmetics and many other similar products for E. coli, coliform and other bacteria.

Color

13906 White with green grid
11406 White with black grid

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic

Pore Size (ISO 7704)

0.45 µm

Structure

Symmetric

Applications and Features

Typical Applications

Microbiological testing of water, pharmaceuticals, foods, beverages and similar products for E. coli, coliform bacteria and other microorganisms were stained colonies and their surroundings require evaluation.

Special Features

- Excellent growth medium
- Perfect development of the typical colony morphology of bacteria on all culture media
- good contrast to dark particles

Technical Advantages

- Does not inhibit growth at grid
- Allow perfect development of typical color reaction of colonies on selective nutrient media.

Typical Performance

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and other organic solvents.

Flow Rate for Water per cm² (DIN 58355)

70 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods

Autoclaving at 121°C, ETO sterilization, γ-irradiation (25 kGy)

Thermal Resistance

130°C max.

Thickness (DIN 53105)

115–145 µm

Growth Promotion Test (ISO 7704)

Bacterial recovery testing has shown that the grid lines do not enhance or inhibit the growth of microorganisms. Recovery rates of total and coliform bacteria indicate that there is no influence on bacterial growth and development due to chemical extractables.

pH of Filter Extract

< 8.3

Coliform Retention

100%

Recovery Rate, Lot-released (DIN 7704)

≥ 90%

Sterility (AC)

Zero growth

Order Numbers

47 mm diameter:

13906-047N, pack of 100
13906-047R, pack of 1000
13906-047ACN, pack of 100 individual sterile packed
13906-047ACR, pack of 1000 individual sterile packed

50 mm diameter:

13906-050N, pack of 100
13906-050R, pack of 1000
13906-050ACN, pack of 100 individual sterile packed
13906-050ACR, pack of 1000 individual sterile packed

Dispenser filters

47 mm diameter:

13906Z-047SCM, pack of 300 pleated without protective disc

50 mm diameter:

13906Z-050SCM, pack of 300 pleated without protective disc

25 mm diameter:

11406-025N, pack of 100

47 mm diameter:

11406-047N, pack of 100
11406-047R, pack of 1000
11406-047ACN, pack of 100 individual sterile packed
11406-047ACR, pack of 1000 individual sterile packed

50 mm diameter:

11406-050N, pack of 100
11406-050ACN, pack of 100 individual sterile packed
11406-050ACR, pack of 1000 individual sterile packed

Dispenser filter

47 mm diameter:

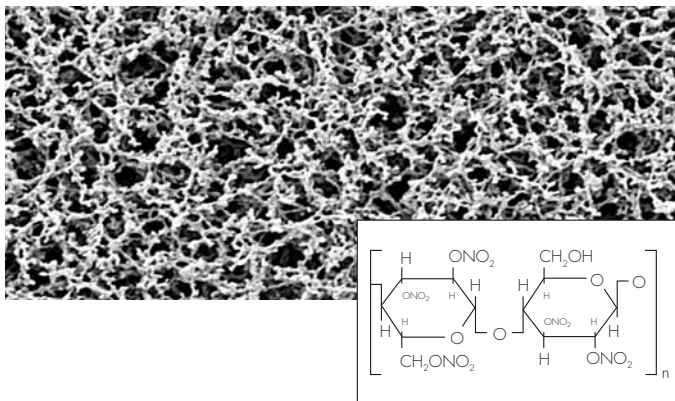
11406-047SCM, pack of 300 in rolls with protective disc
11406Z-047SCM, pack of 300 pleated without protective disc

50 mm diameter:

11406-050SCM, pack of 300 in rolls, with protective disc
11406Z-050SCM, pack of 300 pleated without protective disc

3.1 Cellulose Nitrate Membranes

Type 13106; White with Hydrophobic Edge, Black Grid, 0.45 μm



Description

Gridded cellulose nitrate membrane with hydrophobic edges are the optimal, and most commonly used filters for microbiological testing of samples that contain inhibitors.

Color

White with black grid and pink hydrophobic edge

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic with hydrophobic edge

Pore Size (ISO 7704)

0.45 μm

Structure

Symmetric

Applications and Features

Typical Applications

Microbiological testing of samples that contain antibiotics, disinfectants or other inhibitory substances.

Special Features

- Excellent growth medium
- The hydrophobic edge prevents the diffusion of inhibitors into the membrane filter and protects from reduced growth of microorganisms.

Technical Advantages

- Does not inhibit growth at grid
- Inhibitors can be easily washed out after the filtration.

Typical Performance

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and other organic solvents.

Flow Rate for Water per cm² (DIN 58355)

70 ml/min at $\Delta p = 1 \text{ bar} \mid \sim 15 \text{ psi}$

Sterilization Methods

Autoclaving at 121 °C, ETO sterilization, γ -irradiation (25 kGy)

Thermal Resistance

130 °C max.

Thickness (DIN 53105)

115–145 μm

Growth Promotion Test (ISO 7704)

Bacterial recovery testing has shown that the grid lines do not enhance or inhibit the growth of microorganisms. Recovery rates of total and coliform bacteria indicate that there is no influence on bacterial growth and development due to chemical extractables.

pH of Filter Extract

< 8.3

Coliform Retention

100%

Recovery Rate, Lot-released (DIN 7704)

$\geq 90\%$

Sterility (AC)

Zero growth

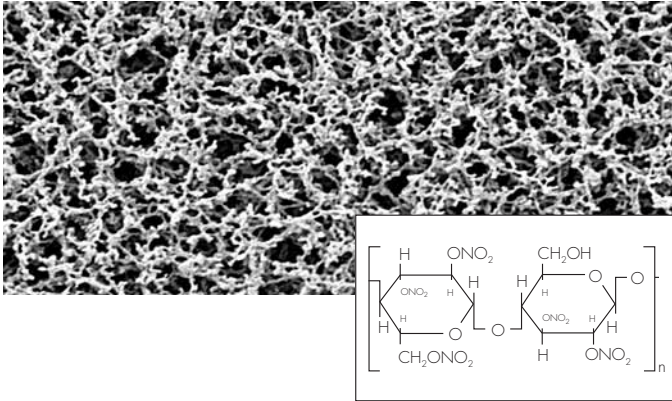
Order Numbers

25 mm diameter:
13106-025N, pack of 100

47 mm diameter:
13106-047N, pack of 100
13106-047HCN, pack of 100 with 6 mm hydrophobic edge
13106-047ACN, pack of 100 individual sterile packed
13106-047HEN, pack of 100 with 6 mm hydrophobic edge individual sterile packed

50 mm diameter:
13106-050N, pack of 100
13106-050ACN, pack of 100 individual sterile packed

3.1 Cellulose Nitrate Membranes Type 13006; Black, White Grid, 0.45 µm



Order Numbers

25 mm diameter:
13006-025N, pack of 100

47 mm diameter:
13006-047N, pack of 100
13006-047ACN, pack of 100
individual sterile packed
13006-047ACR, pack of 1000
individual sterile packed

50 mm diameter:
13006-050N, pack of 100
13006-050ACN, pack of 100
individual sterile packed
13006-050ACR, pack of 1000
individual sterile packed

Description

Gridded cellulose nitrate membranes are the optimal, and most commonly used filters for microbiological testing of water, beverages, foods, pharmaceuticals, cosmetics and many other similar products.

Color

Gray, white grid; turns black after wetting

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic

Pore Size (ISO 7704)

0.45 µm

Structure

Symmetric

Applications and Features

Typical Applications

Microbiological testing of water, pharmaceuticals, cosmetics, foods, beverages and other products for yeasts and molds. Especially recommended for the detection of Legionella.

Special Features

- Excellent growth medium
- The gray color turns black when the filter is wetted.

Technical Advantages

- Does not inhibit growth at grid
- Perfect contrast to the mainly white colonies of yeasts and of the vegetative growing colonies of the molds

Typical Performance

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and other organic solvents.

Flow Rate for Water per cm² (DIN 58355)

70 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods

Autoclaving at 121°C, ETO sterilization, γ-irradiation (25 kGy)

Thermal Resistance

130°C max.

Thickness (DIN 53105)

115–145 µm

Growth Promotion Test (ISO 7704)

Bacterial recovery testing has shown that the grid lines do not enhance or inhibit the growth of microorganisms. Recovery rates of total and coliform bacteria indicate that there is no influence on bacterial growth and development due to chemical extractables.

pH of Filter Extract

< 8.3

Coliform Retention

100%

Recovery Rate, Lot-released (DIN 7704)

≥ 90%

Sterility (AC)

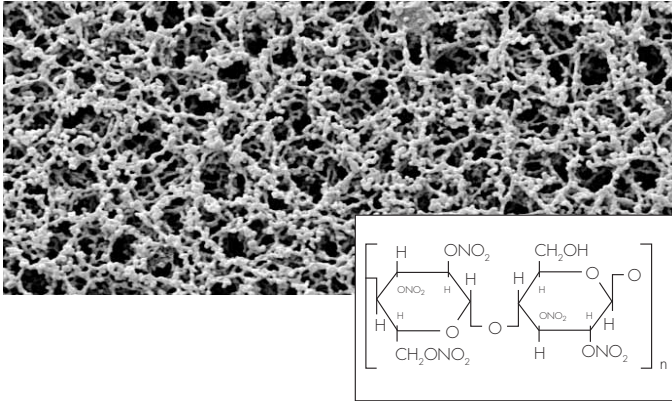
Zero growth

Dispenser filters

47 mm diameter:
13006-047SCM, pack of 300
in rolls with protective disc
13006Z-047SCM, pack of 300
pleated without protective disc

50 mm diameter:
13006-050SCM, pack of 300
in rolls with protective disc
13006Z-050SCM, pack of 300
pleated without protective disc

3.1 Cellulose Nitrate Membranes Type 13806; Green Membrane, Green Grid, 0.45 µm



Order Numbers

47 mm diameter:
 13806-047N, pack of 100
 13806-047R, pack of 1000
 13806-047ACN, pack of 100
 individual sterile packed
 13806-047ACR, pack of 1000
 individual sterile packed

50 mm diameter:
 13806-050N, pack of 100
 13806-050R, pack of 1000
 13806-050ACN, pack of 100
 individual sterile packed
 13806-050ACR, pack of 1000
 individual sterile packed

Description

Gridded cellulose nitrate membranes are the optimal, and most commonly used filters for microbiological testing of water, beverages, foods, pharmaceuticals, cosmetics and many other similar products.

Color

Green, green grid

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic

Pore Size (ISO 7704)

0.45 µm

Structure

Symmetric

Applications and Features

Typical Applications

Microbiological testing of water, pharmaceutical products, foods, beverages and similar products.

Special Features

- Excellent growth medium
- Allows perfect development of the typical colony morphology of bacteria on all culture media

Technical Advantages

- Does not inhibit growth at grid
- Provides good contrast to the colorless or white colonies of many bacteria on non-selective nutrient media.

Typical Performance

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents

Flow Rate for Water per cm² (DIN 58355)

70 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods

Autoclaving at 121 °C, ETO sterilization, γ-irradiation (25 kGy)

Thermal Resistance

130°C max.

Thickness (DIN 53105)

115–145 µm

Growth Promotion Test (ISO 7704)

Bacterial recovery testing has shown that the grid lines do not enhance or inhibit the growth of microorganisms. Recovery rates of total and coliform bacteria indicate that there is no influence on bacterial growth and development due to chemical extractables.

pH of Filter Extract

< 8.3

Coliform Retention

100%

Recovery Rate, Lot-released (DIN 7704)

≥ 90%

Sterility (AC)

Zero growth

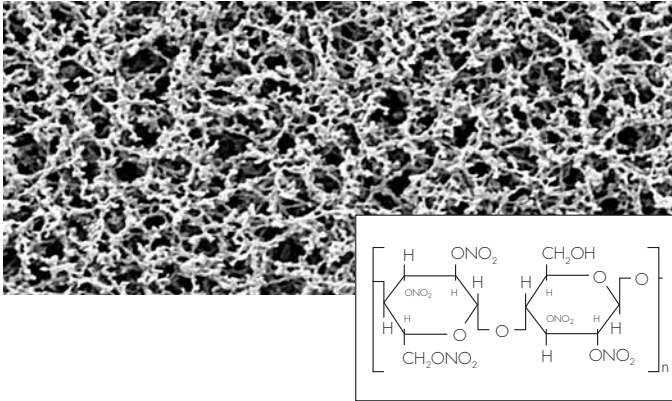
Dispenser filters

47 mm diameter:
 13806-047SCM, pack of 300
 in rolls with protective disc
 13806Z-047SCM, pack of 300
 pleated without protective disc

50 mm diameter:

13806-050SCM, pack of 300
 in rolls with protective disc
 13806Z-050SCM, pack of 300
 pleated without protective disc

3.1 Cellulose Nitrate Membranes Type 11407; White, Black Grid, 0.2 µm



Order Numbers

25 mm diameter:
11407-025N, pack of 100

47 mm diameter:
11407-047N, pack of 100
11407-047R, pack of 1000
11407-047ACN, pack of 100
individual sterile packed
11407-047ACR, pack of 1000
individual sterile packed

50 mm diameter:
11407-050N, pack of 100
11407-050ACN, pack of 100
individual sterile packed
11407-050ACR, pack of 1000
individual sterile packed

Description

Gridded cellulose nitrate filter material is the optimal membrane filter for the microbiological detection of bacteria. The membrane filters with pore size 0.2 µm also allow complete retention and reliable recovery of extremely small water-borne microbes in pharmaceutical applications.

Color

White with black grid

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic

Pore Size (Nominal)

0.2 µm

Structure

Symmetric

Applications and Features

Typical Applications

Detection of the total bacteria count in water for pharmaceutical applications.

Special Features

- Fine, uniform pore structure
- High, non-specific adsorption.

Technical Advantages

Provides optimal growth characteristics for microorganisms and absolute retention of all bacteria.

Typical Performance

Non-specific Adsorption

The non-specific adsorption decreases with increasing pore size, see example for γ -globulin.

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents

Flow Rate for Water per cm² (DIN 58355)

20 ml/min at $\Delta p = 1 \text{ bar} \mid \sim 15 \text{ psi}$

Sterilization Methods

Autoclaving at 121°C, ETO sterilization, γ -irradiation (25 kGy)

Thermal Resistance

130°C max.

Thickness (acc. to DIN 53105)

115–145 µm

Growth Promotion Test (ISO 7704)

Bacterial recovery testing has shown that the grid lines do not enhance or inhibit the growth of microorganisms. Recovery rates of total and coliform bacteria indicate that there is no influence on bacterial growth and development due to chemical extractables.

pH of Filter Extract

< 8.3

Coliform Retention

100%

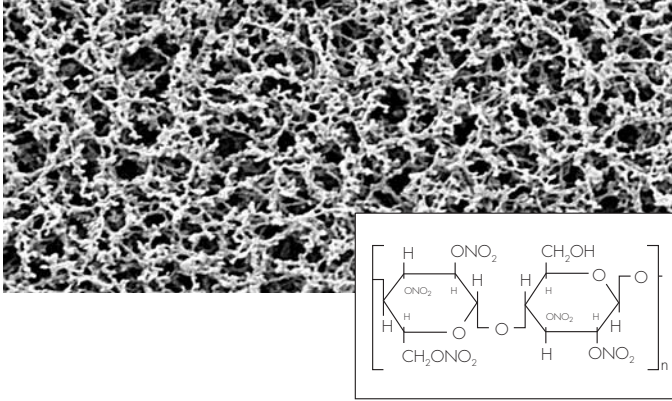
Recovery Rate, Lot-released (DIN 7704)

≥ 90%

Sterility (AC)

Zero growth

3.1 Cellulose Nitrate Membranes Type 13107; White with Hydrophobic Edge, Black Grid, 0.2 μm



Order Numbers

25 mm diameter:
13107-025N, pack of 100

47 mm diameter:
13107-047N, pack of 100
13107-047HCN, pack of 100
with 6 mm pink-colored
hydrophobic edge
13107-047ACN, pack of 100
individual sterile packed

50 mm diameter:
13107-050N, pack of 100
13107-050ACN, pack of 100
individual sterile packed

Description

Gridded cellulose nitrate filter material with hydrophobic edge is the optimal membrane filter for the microbiological testing of samples that contain inhibitors. The membrane filters with pore size 0.2 μm also allow complete retention and reliable recovery of extremely small water-borne microbes in pharmaceutical applications.

Color

White with black grid and pink hydrophobic edge

Material

Cellulose nitrate (cellulose ester)

Reaction to Water

Hydrophilic with hydrophobic edge

Pore Size (Nominal)

0.2 μm

Structure

Symmetric

Applications and Features

Typical Applications

Detection of the total bacteria count in samples that contain disinfectants, antibiotics or other inhibitors.

Special Features

– The hydrophobic edge prevents the diffusion of inhibitors into the membrane and protects from reduced growth.

Technical Advantages

Provides optimal growth characteristics for microorganisms, and absolute retention of all bacteria.

Typical Performance

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents

Flow Rate for Water per cm² (DIN 58355)

20 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods

Autoclaving at 121 °C, ETO sterilization, γ-irradiation (25 kGy)

Thermal Resistance

130°C max.

Thickness (acc. to DIN 53105)

115–145 μm

Growth Promotion Test (ISO 7704)

Bacterial recovery testing has shown that the grid lines do not enhance or inhibit the growth of microorganisms. Recovery rates of total and coliform bacteria indicate that there is no influence on bacterial growth and development due to chemical extractables.

pH of Filter Extract

< 8.3

Coliform Retention

100%

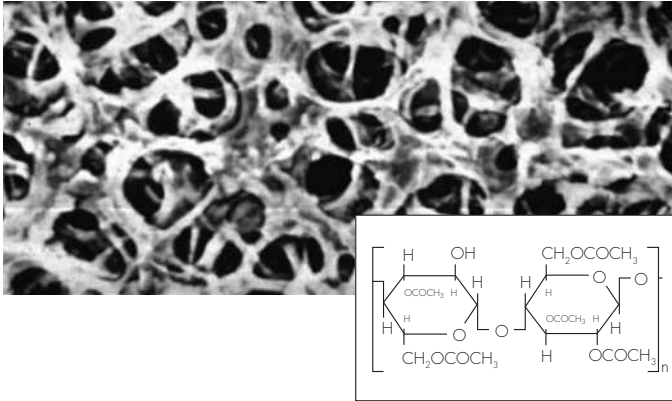
Recovery Rate, Lot-released (DIN 7704)

≥ 90%

Sterility (AC)

Zero growth

3.2 Cellulose Acetate Membranes Type 12342, 5.0 µm



Order Numbers

25 mm diameter:
12342-025N, pack of 100

47 mm diameter:
11104-047N, pack of 100

142 mm diameter:
12342-142G, pack of 25

Description

Cellulose acetate membranes combine high flow rates and thermal stability with very low adsorption characteristics. The 5.0 µm membrane is used for the coarse particle filtration in samples where a low adsorption is required. The membrane is excellently suited for use in pressure filtration devices.

Color

White

Material

Cellulose acetate

Reaction to Water

Hydrophilic

Pore Size (Nominal)

5.0 µm

Structure

Symmetric

Applications and Features

Typical Applications

Particle reduction of liquid samples where no non-specific adsorption can be tolerated. Prefiltration of water with a high particle load, of media and similar samples.

Special Features

- Very low non-specific adsorption
- Excellent thermal resistance

Technical Advantages

- Minimum loss of proteins, preservatives etc.
- Autoclavable at 121°C or 134°C
- Dry heat sterilization possible
- Reliable sterile filtration

Typical Performance

Adsorption, Non-specific

Bovine serum albumin
< 10 µg/cm²

Bubble Point with Water (DIN 58355)

0.4 bar | ~ 6 psi

Burst Pressure

0.2 bar | ~ 3 psi

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), oils, alcohols and other organic solvents.

Extractables with Water

< 10%

Flow Rate for Air [L/m²/s 200 Pa] according to*

23.0

corresponding water flow rate:

approx. 570 ml/min at Δp = 1 bar | ~ 14.5 psi

Sterilization Methods

Autoclaving at 121°C or 134°C, dry-heat sterilization at 160°C, ETO sterilization, γ-irradiation (25 kGy)

Thermal Resistance

180°C max.

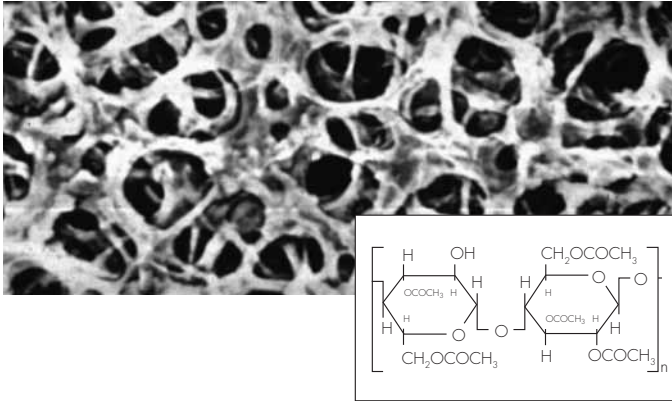
Thickness (DIN 53105)

Approx. 140 µm

* ASTM D737
DIN 53'887
ISO 9'237

3.2 Cellulose Acetate Membranes

Type 12303, 1.2 μm



Description

Cellulose acetate membranes combine high flow rates and thermal stability with very low adsorption characteristics. The 1.2 μm membrane is used for the particle filtration in samples where a low adsorption is required. The membrane is excellently suited for use in pressure filtration devices.

Color
White

Material
Cellulose acetate

Reaction to Water
Hydrophilic

Pore Size (Nominal)
1.2 μm

Structure
Symmetric

Applications and Features

Typical Applications

Particle reduction of liquid samples where no non-specific adsorption can be tolerated. Prefiltration of water with a high particle load, of media and similar samples.

Special Features

- Very low non-specific adsorption
- Excellent thermal resistance

Technical Advantages

- Minimum loss of proteins, preservatives etc.
- Autoclavable at 121°C or 134°C
- Dry heat sterilization possible
- Reliable sterile filtration

Typical Performance

Adsorption, Non-specific
Bovine serum albumin
< 10 $\mu\text{g}/\text{cm}^2$

Bubble Point with Water (DIN 58355)
0.8 bar | ~ 11 psi

Burst Pressure
0.4 bar | ~ 6 psi

Chemical Compatibility
Compatible with aqueous solutions (pH 4–8), oils, alcohols and several other organic solvents

Extractables with Water
< 10%

Flow Rate for Air [L/m²/s 200 Pa] according to*
9.0
corresponding water flow rate:
approx. 320 ml/min at $\Delta p = 1 \text{ bar}$ | ~ 14.5 psi

Sterilization Methods
Autoclaving at 121°C or 134°C, dry-heat sterilization at 160°C, ETO sterilization, γ -irradiation (25 kGy)

Thermal Resistance
180°C max.

Thickness (DIN 53105)
Approx. 140 μm

Order Numbers

25 mm diameter:
12303-025N, pack of 100

47 mm diameter:
12303-047N, pack of 100

50 mm diameter:
12303-050N, pack of 100

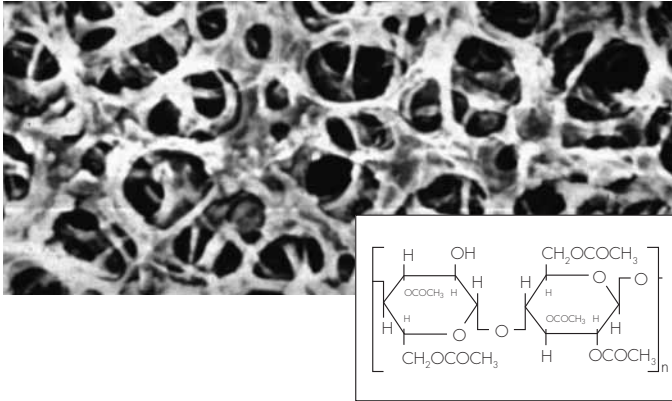
100 mm diameter:
12303-100 G, pack of 25

142 mm diameter:
12303-142G, pack of 25

293 mm diameter:
12303-293G, pack of 25

* ASTM D737
DIN 53'887
ISO 9'237

3.2 Cellulose Acetate Membranes Type 11104, 0.8 µm



Order Numbers

13 mm diameter:
11104-013N, pack of 100

25 mm diameter:
11104-025N, pack of 100

47 mm diameter:
11104-047N, pack of 100

50 mm diameter:
11104-050N, pack of 100

142 mm diameter:
11104-142G, pack of 25
11104-142N, pack of 100

293 mm diameter:
11104-293G, pack of 25
11104-293N, pack of 100

Description

Cellulose acetate membranes combine high flow rates and thermal stability with very low adsorption characteristics. The 0.8 µm membrane is used for the particle filtration in samples where a low adsorption is required. The membrane is excellently suited for use in pressure filtration devices.

Color

White

Material

Cellulose acetate

Reaction to Water

Hydrophilic

Pore Size (Nominal)

0.8 µm

Structure

Symmetric

Applications and Features

Typical Applications

Particle reduction of liquid samples where no non-specific adsorption can be tolerated. Prefiltration of water with a high particle load, of media and similar samples.

Special Features

- Very low non-specific adsorption
- Excellent thermal resistance

Technical Advantages

- Minimum loss of proteins, preservatives etc.
- Autoclavable at 121°C or 134°C
- Dry heat sterilization possible
- Reliable sterile filtration

Typical Performance

Adsorption, Non-specific

Bovine serum albumin
< 10 µg/cm²

Bubble Point with Water (DIN 58355)

1.0 bar | ~ 14 psi

Burst Pressure

0.3 bar | ~ 4.4 psi

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), oils, alcohols and several other organic solvents

Extractables with Water

< 1%

Flow Rate for Air [L/m²/s 200 Pa] according to*

5.3

corresponding water flow rate: approx.
200 ml/min at Δp = 1 bar | ~14.5 psi

Sterilization Methods

Autoclaving at 121°C or 134°C, dry-heat sterilization at 160°C, ETO sterilization, γ-irradiation (25 kGy)

Thermal Resistance

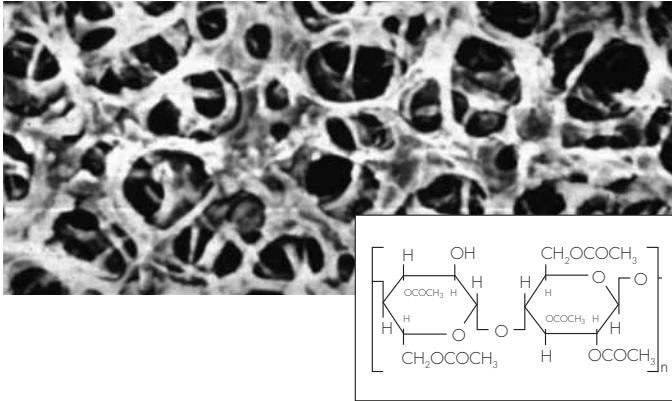
180°C max.

Thickness (DIN 53105)

Approx. 120 µm

* ASTM D737
DIN 53'887
ISO 9'237

3.2 Cellulose Acetate Membranes Type 11105, 0.65 μm



Order Numbers

25 mm diameter:
11105-025N, pack of 100

47 mm diameter:
11105-047N, pack of 100

50 mm diameter:
11105-050N, pack of 100

142 mm diameter:
11105-142G, pack of 25

293 mm diameter:
11105-293G, pack of 25

Description

Cellulose acetate membranes combine high flow rates and thermal stability with very low adsorption characteristics. The 0.65 μm membrane is used in many applications for the reduction of the particle content without losing ingredients by adsorption. The membrane is excellently suited for use in pressure filtration devices

Color

White

Material

Cellulose acetate

Reaction to Water

Hydrophilic

Pore Size (Nominal)

0.65 μm

Structure

Symmetric

Applications and Features

Typical Applications

Prefiltration of water, culture media, solutions containing antibiotics or proteins, particle filtration of many samples where non-specific adsorption is not desired.

Special Features

- Very low non-specific adsorption
- Excellent thermal resistance

Technical Advantages

- Minimum loss of proteins, preservatives etc.
- Autoclavable at 121°C or 134°C
- Dry heat sterilization possible

Typical Performance

Adsorption, Non-specific

Bovine serum albumin
10 $\mu\text{g}/\text{cm}^2$

Bubble Point with Water (DIN 58355)

1.5 bar | ~ 22 psi

Burst Pressure

0.3 bar | ~ 4.4 psi

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), oils, alcohols and several other organic solvents

Extractables with Water

< 1%

Flow Rate for Water per cm^2 (DIN 58355)

115 ml/min at $\Delta p = 1$ bar | ~ 15 psi

Sterilization Methods

Autoclaving at 121°C or 134°C, dry-heat sterilization at 160°C, ETO sterilization, γ -irradiation (25 kGy)

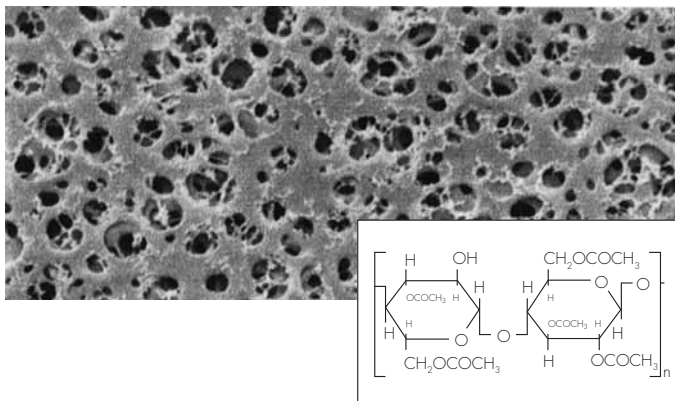
Thermal Resistance

180°C max.

Thickness (DIN 53105)

Approx. 120 μm

3.2 Cellulose Acetate Membranes Type 11106, 0.45 µm



Description

Cellulose acetate membranes combine high flow rates and thermal stability with very low adsorption characteristics. The 0.45 µm membrane is a very convenient filter type for the reduction of particles and microorganisms in aqueous solutions such as nutrient media, buffers, sera and similar samples. The membrane is excellently suited for use in pressure filtration devices

Color
White

Material
Cellulose acetate

Reaction to Water
Hydrophilic

Pore Size (Nominal)
0.45 µm

Structure
Symmetric

Applications and Features

Typical Applications
Microbe-retentive, particle-removing filtration of nutrient media, water and solutions containing antibiotics or proteins; sterility testing, colony counting.

Special Features
– Very low non-specific adsorption
– Excellent thermal resistance

Technical Advantages
– Minimum loss of proteins, preservatives etc.
– Autoclavable at 121°C or 134°C
– Dry heat sterilization possible

Typical Performance

Adsorption, Non-specific
Bovine serum albumin
10 µg/cm²

Bubble Point with Water (DIN 58355)
2.4 bar | ~ 35 psi

Burst Pressure
> 0.4 bar | ~ 5.8 psi

Chemical Compatibility
Compatible with aqueous solutions (pH 4–8), oils, alcohols and several other organic solvents

Extractables with Water
< 1%

Flow Rate for Water per cm² (DIN 58355)
65 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods
Autoclaving at 121°C or 134°C, dry-heat sterilization at 160°C, ETO sterilization, γ-irradiation (25 kGy)

Thermal Resistance
180°C max.

Thickness (DIN 53105)
Approx. 120 µm

Tests According to USP Standards

Absence of Pyrogens (Endotoxin Content)
Passed

Biological Testing (Plastic Class VI)
Passed

Order Numbers

13 mm diameter:
11106-013N, pack of 100

25 mm diameter:
11106-025N, pack of 100

30 mm diameter:
11106-030N, pack of 100

47 mm diameter:
11106-047N, pack of 100
11106--47----ACN, pack of 100

50 mm diameter:
11106-050N, pack of 100
11106--50----ACN, pack of 100

85 mm diameter:
11106-085N, pack of 100

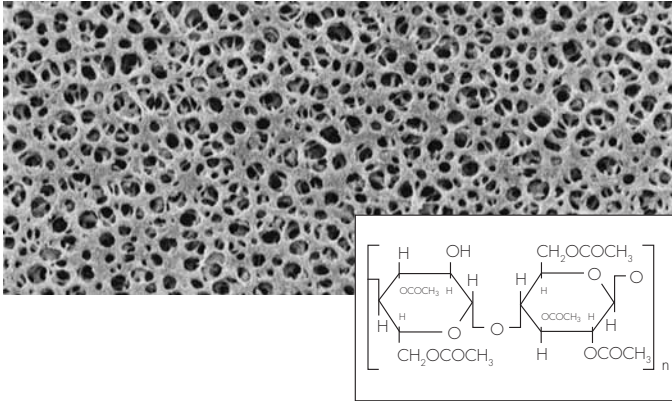
90 mm diameter:
11106-090G, pack of 25

100 mm diameter:
11106-100G, pack of 25
11106-100N, pack of 100

142 mm diameter:
11106-142G, pack of 25
11106-142N, pack of 100

293 mm diameter:
11106-293G, pack of 25
11106-293N, pack of 100

3.2 Cellulose Acetate Membranes Type 11107, 0.2 µm



Description

Cellulose acetate membranes combine high flow rates and thermal stability with very low adsorption characteristics. The 0.2 µm membrane is the filter of choice for sterile filtration of aqueous solutions such as nutrient media, buffers and sera. The membranes are excellently suited for use in pressure filtration devices.

Color

White

Material

Cellulose acetate

Reaction to Water

Hydrophilic

Pore Size (Nominal)

0.2 µm

Structure

Symmetric

Applications and Features

Typical Applications

Sterile filtration of water, culture media, solutions containing antibiotics or proteins, cell harvesting.

Special Features

- Very low non-specific adsorption
- Excellent thermal resistance
- Validated using *Brevundimonas diminuta*

Technical Advantages

- Minimum loss of proteins, preservatives etc.
- Autoclavable at 121°C or 134°C
- Dry heat sterilization possible
- Reliable sterile filtration

Typical Performance

Adsorption, Non-specific

Bovine serum albumin
< 10 µg/cm²

Bubble Point with Water

2.9 bar | ~ 42 psi
(when measured with an automatic integrity tester)

Burst Pressure

0.5 bar | ~ 7 psi

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), oils, alcohols and several other organic solvents

Extractables with Water

< 1%

Flow Rate for Water per cm² (DIN 58355)

20 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods

Autoclaving at 121°C or 134°C, dry-heat sterilization at 160°C, ETO sterilization, γ-irradiation (25 kGy)

Thermal Resistance

180°C max.

Thickness (DIN 53105)

Approx. 120 µm

Sterility (AC)

Zero growth

Tests According to USP Standards

Absence of Pyrogens (Endotoxin Content)

Passed

Biological Testing (Plastic Class VI)

Passed

Extractables

Passed test after standard flushing

Particle Release

Passed

Retentive Capacity

100% retention of *Brevundimonas diminuta*, ATCC 19146 test organisms (10⁷/cm² filter area)

Order Numbers

13 mm diameter:
11107-013N, pack of 100

25 mm diameter:
11107-025N, pack of 100

30 mm diameter:
11107-030N, pack of 100

47 mm diameter:
11107-047N, pack of 100

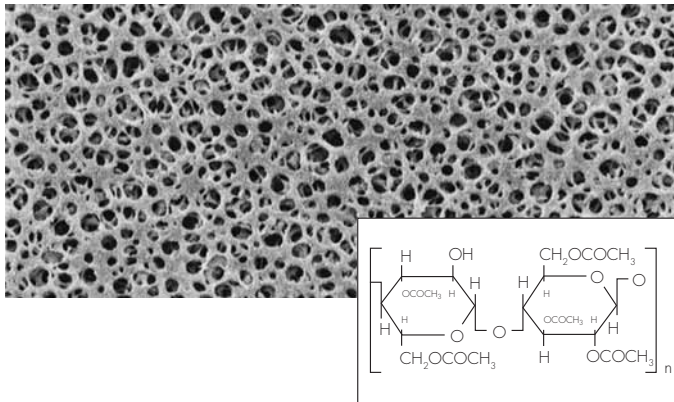
50 mm diameter:
11107-050N, pack of 100
11107-050ACN, pack of 100
individual sterile packed

100 mm diameter:
11107-100G, pack of 25
11107-100N, pack of 100

142 mm diameter:
11107-142G, pack of 25
11107-142N, pack of 100

293 mm diameter:
11107-293G, pack of 25
11107-293N, pack of 100

3.2 Cellulose Acetate Membranes Type 13507 and 13506; Hydrophobic Edge, 0.2 µm, 0.45 µm



Order Numbers

47 mm diameter:
 13507-047N, pack of 100
 13507-047ACN, pack of 100 individual sterile packed
 13506-047N, pack of 100
 13506-047ACN, pack of 100 individual sterile packed
 13506-047HCN, pack of 100, 6 mm hydrophobic edge

50 mm diameter:
 13506-050ACN, pack of 100 individual sterile packed

Description

Cellulose acetate membranes combine high flow rates and thermal stability with low adsorption characteristics. The version with a hydrophobic edge is mainly used for the sterility testing in re-usable filter holders because the hydrophobic edge prevents diffusion of inhibitors into the membrane filter.

Color

White

Material

Cellulose acetate

Reaction to Water

Hydrophilic with hydrophobic edge

Pore Size

13507 0.2 µm
 13506 0.45 µm

Structure

Symmetric

Applications and Features

Typical Applications

Sterility testing of pharmaceutical products by means of the liquid enrichment procedure. The membrane is incubated in or under tryptic soy or thioglycolate broth.

Special Features

– Very low non-specific adsorption combined with the hydrophobic edge prevents the presence of inhibitors during sterility testing.

Technical Advantages

– Autoclavable at 121°C or 134°C
 – Dry heat sterilization possible
 – Reliable retention of microorganism acc. to USP and EP requirements.

Typical Performance

Adsorption, Non-specific

Bovine serum albumin
 $< 10 \mu\text{g}/\text{cm}^2$; $1 \mu\text{g}/\text{cm}^2$

Bubble Point with Water:

13507: min. 2.9 bar | ~ 42 psi
 when measured with an automatic integrity test instrument
 13506: 2 bar | ~ 29 psi (acc. to DIN 58355)

Burst Pressure

13507: 0.5 bar | ~ 5.8 psi
 13506: 0.4 bar | ~ 4.4 psi

Chemical Compatibility

Compatible with aqueous solutions (pH 4–8), oils, alcohols and several other organic solvents

Extractables with Water

$< 1\%$

Flow Rate for Water per cm^2 (DIN 58355)

20 l/min at $\Delta p = 1 \text{ bar}$ | ~ 15 psi
 65 l/min at $\Delta p = 1 \text{ bar}$ | ~ 15 psi

Sterilization Methods

Autoclaving at 121°C or 134°C, dry-heat sterilization at 160°C, ETO sterilization, γ -irradiation (25 kGy)

Thermal Resistance

180°C max.

Thickness (DIN 53105)

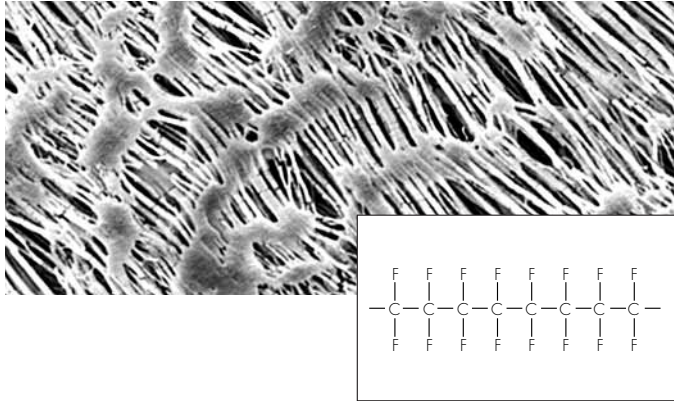
Approx. 120 µm

Tests According to USP Standards

Retentive Capacity

100% retention of *Brevundimonas diminuta*, ATCC 19146 test organisms ($10^7/\text{cm}^2$ filter area) for 13907.

3.3 PTFE Membranes Type 11806, 0.45 μm



Description

Made from pure PTFE (polytetrafluoroethylene), therefore the membranes are permanently hydrophobic and are not wetted by humid air. This feature allows unhindered passage of air even at low differential pressures.

Color
White

Material
PTFE

Reaction to Water
Hydrophobic

Pore Size (Nominal)
0.45 μm

Structure
Symmetric

Applications and Features

Typical Applications

Filtration of air and other gases, acids, bases and solvents where sterility is not required.

Special Features

- Outstanding chemical compatibility
- Permanently hydrophobic
- Excellent thermal resistance

Technical Advantages

- Compatible with almost all acids, bases and solvents
- Autoclavable at 121°C or 134°C
- Dry heat sterilization possible
- Unimpeded air passage even at low differential pressures

Typical Performance

Bubble Point with Isopropanol (DIN 58355)
0.8 bar | \sim 12 psi

Chemical Compatibility
Compatible with solvents, acids and bases.

Extractables with Isopropanol
< 1%

Flow Rate for Isopropanol per cm^2
20 ml/min at $\Delta p = 1$ bar | \sim 15 psi

Sterilization Methods
Autoclaving at 121°C or 134°C, dry-heat sterilization at 160°C or 180°C, ETO sterilization

Thermal Resistance
200°C max.

Thickness (DIN 53105)
Approx. 80 μm

Order Numbers

13 mm diameter:
11806-013N, pack of 100

25 mm diameter:
11806-025N, pack of 100

47 mm diameter:
11806-047N, pack of 100

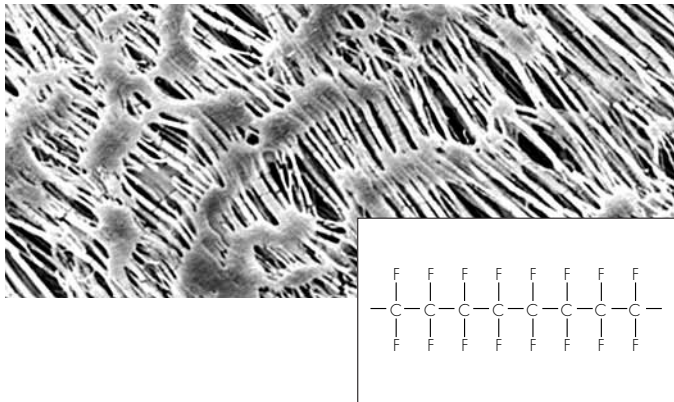
50 mm diameter:
11806-050N, pack of 100

100 mm diameter:
11806-100G, pack of 25

142 mm diameter:
11806-142G, pack of 25

293 mm diameter:
11806-293G, pack of 25

3.3 PTFE Membranes Type 11807, 0.2 µm



Description

Made from pure PTFE (polytetrafluoroethylene), therefore the membranes are permanently hydrophobic and are not wetted by humid air. This feature allows unhindered passage of air even at low differential pressures.

Color

White

Material

PTFE

Reaction to Water

Hydrophobic

Pore Size (Nominal)

0.2 µm

Structure

Symmetric

Applications and Features

Typical Applications

Sterile filtration of air and other gases, acids, bases and solvents.

Special Features

- Outstanding chemical compatibility
- Permanently hydrophobic
- Excellent thermal resistance
- Validated using *Brevundimonas diminuta*

Technical Advantages

- Compatible with almost all acids, bases and solvents.
- Autoclavable at 121°C or 134°C
- Dry heat sterilization possible
- Unimpeded air passage even at low differential pressures
- Reliable sterile filtration

Typical Performance

Bubble Point with Isopropanol (DIN 58355)

1.0 bar | ~ 15 psi

Chemical Compatibility

Compatible with solvents, acids and bases.

Extractables with Isopropanol

< 1%

Flow Rate for Isopropanol per cm²

11 ml/min at $\Delta p = 1$ bar | ~15 psi

Sterilization Methods

Autoclaving at 121°C or 134°C, dry-heat sterilization at 160°C or 180°C, ETO sterilization

Sterilizing Filtration

Filters with 0.2 µm pore size are validated with the Bacteria Challenge Test

Thermal Resistance

200°C max.

Thickness (DIN 53105)

Approx. 65 µm

Retentive Capacity

100% retention of *Brevundimonas diminuta*, ATCC 19146 test organisms (10⁷/cm² filter area)

Order Numbers

13 mm diameter:
11807-013N, pack of 100

25 mm diameter:
11807-025N, pack of 100

47 mm diameter:
11807-047N, pack of 100

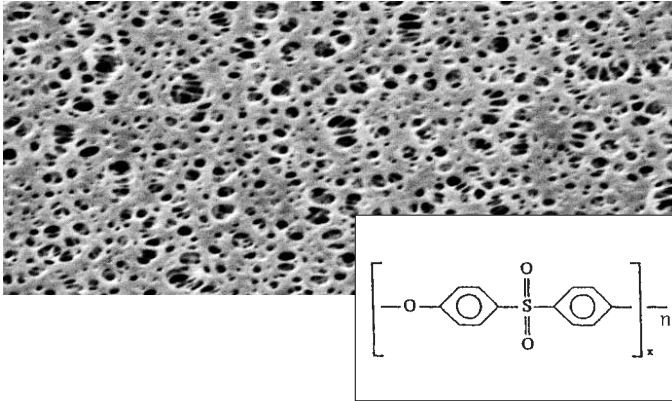
50 mm diameter:
11807-050N, pack of 100

100 mm diameter:
11807-100G, pack of 25

142 mm diameter:
11807-142G, pack of 25

293 mm diameter:
11807-293G, pack of 25

3.4 Polyethersulfone Membranes Type 15406, 0.45 µm



Description

Polyethersulfone (PES) filters have a high internal porosity. They perform well at high flux with an excellent throughput of aqueous solutions over the entire pH range of 1–14. The low level of extractables from PES membranes makes them suitable for environmental analysis.

Color
White

Material
PES

Reaction to Water
Hydrophilic

Pore Size (Nominal)
0.45 µm

Structure
Symmetric

Applications and Features

Typical Applications

Filtration of biological and pharmaceutical solutions where sterility is not required. Environmental analysis.

Special Features

- Very good chemical compatibility
- Low level of extractables
- Low non-specific protein adsorption

Technical Advantages

- Resistant over pH range 1–14
- Very fast flow rate

Typical Performance

Adsorption

~ 10 µg/cm², non-specific for γ-globulin
< 8 µg/cm² for BSA

Bubble Point with Water (Sartocheck)
2.6 bar | 38 psi

Burst Pressure
0.7 bar | ~ 10 psi

Chemical Compatibility
Resistant to aggressive aqueous solutions, pH 1–14.

Flow Rate for Water per cm²
46 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods
Autoclaving at 121°C or 134°C,
gamma-radiation
ETO sterilization

Thermal Resistance
200°C max.

Thickness (DIN 53105)
Approx. 150 µm

Tests According to USP Standards

Absence of Pyrogens (Endotoxin Content)
Passed

Biological Testing (Plastic Class VI)
Passed

Extractables
Passed test after standard flushing

Particle Release
Passed

Retentive Capacity
100% retention of *Serratia marcescens*
(10⁷/cm² filter area)

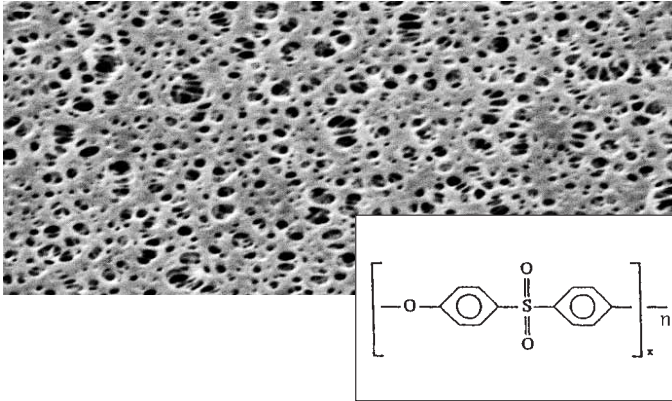
Order Numbers

25 mm diameter:
15406-025N, pack of 100

47 mm diameter:
15406-047N, pack of 100

50 mm diameter:
15406-050N, pack of 100

3.4 Polyethersulfone Membranes Type 15407MI, 0.2 µm



Description

Polyethersulfone (PES) filters have a high internal porosity. They perform well at high flux with an excellent throughput of aqueous solutions over the entire pH range of 1–14. Thanks to their low non-specific protein adsorption the PES type is recommended for filtering biological and pharmaceutical solutions.

Color

White

Material

PES

Reaction to Water

Hydrophilic

Pore Size (Nominal)

0.2 µm

Structure

Symmetric

Applications and Features

Typical Applications

Sterile filtration of biological and pharmaceutical solutions.

Special Features

- Very good chemical compatibility
- Low level of extractables
- Low non-specific protein adsorption

Technical Advantages

- Resistant over pH range 1–14
- Very fast flow rate
- Reliable sterile filtration

Typical Performance

Adsorption, Non-specific

~10 µg/cm² for γ-globulin
< 8 µg/cm² for BSA

Bubble Point Water (Sartocheck)

3.5 bar | 50 psi

Burst Pressure

0.7 bar | ~ 10 psi

Chemical Compatibility

Resistant to aggressive aqueous solutions, pH 1–14.

Flow Rate for Water per cm²

> 25 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods

Autoclaving at 121°C or 134°C,
gamma-radiation
ETO sterilization

Sterilizing Filtration

Filters with 0.2 µm pore size are validated by the bacteria challenge test

Thermal Resistance

200°C max.

Thickness (DIN 53105)

Approx. 150 µm

Tests According to USP Standards

Absence of Pyrogens (Endotoxin Content)

Passed

Biological Testing (Plastic Class VI)

Passed

Extractables

Passed test after standard flushing

Particle Release

Passed

Retentive Capacity

100% retention of *Brevundimonas diminuta*, ATCC 19146 test organisms (10⁷/cm² filter area)

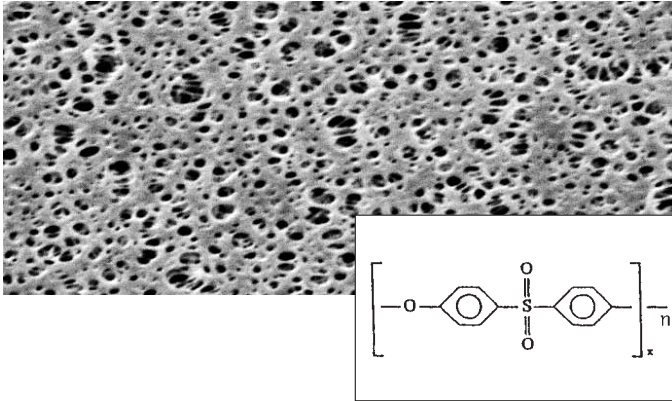
Order Numbers

25 mm diameter:
15407-025MIN, pack of 100

47 mm diameter:
15407-047MIN, pack of 100

50 mm diameter:
15407-050MIN, pack of 100

3.4 Polyethersulfone Membranes Type 15458, 0.1 µm



Description

Polyethersulfone (PES) filters have a high internal porosity. They perform well at high flux with an excellent throughput of aqueous solutions over the entire pH range of 1–14.

Color

White

Material

PES

Reaction to Water

Hydrophilic

Pore Size (Nominal)

0.1 µm

Structure

Symmetric

Applications and Features

Typical Applications

Sterile filtration of biological and pharmaceutical solutions that contain microorganisms smaller than 0.2 µm.

Special Features

- Very good chemical compatibility
- Low level of extractables
- Low non-specific protein adsorption

Technical Advantages

- Resistant over pH range 1–14
- Very fast flow rate
- Reliable sterile filtration

Typical Performance

Adsorption, Non-specific

~15 µg/cm² for γ-globulin
< 10 µg/cm² for BSA

Bubble Point with Isopropanol/water (60:40) (Sartocheck)

2.8 bar | ~ 40psi

Burst Pressure

0.8 bar | ~ 12si

Chemical Compatibility

Resistant to aggressive aqueous solutions

Flow Rate for Water per cm²

10 ml/min at Δp = 1 bar | ~15 psi

Sterilization Methods

Autoclaving at 121°C or 134°C,
gamma-radiation
ETO sterilization

Sterilizing Filtration

Filters with 0.1 µm pore size are validated with the Bacteria Challenge Test

Thermal Resistance

200°C max.

Thickness (DIN 53105)

Approx. 150 µm

Tests According to USP Standards

Absence of Pyrogens (Endotoxin Content)

Passed

Biological Testing (Plastic Class VI)

Passed

Extractables

Passed test after standard flushing

Particle Release

Passed

Retentive Capacity

100% retention of *Brevundimonas diminuta*, ATCC 19146 test organisms (10⁷/cm² filter area)
100% retention of *Mycoplasma*, test organisms (10⁷/cm² filter area)

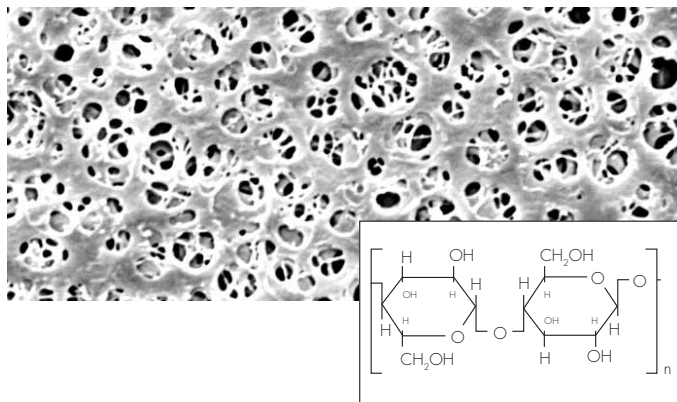
Order Numbers

25 mm diameter:
15458-025N, pack of 100

47 mm diameter:
15458-047N, pack of 100

50 mm diameter:
15458-050N, pack of 100

3.5 Regenerated Cellulose Membranes Type 18406, 0.45 µm



Order Numbers

13 mm diameter:
18467-013N, pack of 100

47 mm diameter:
18406-047N, pack of 100

100 mm diameter:
18406-100G, pack of 25

142 mm diameter:
18406-142G, pack of 25

293 mm diameter:
18406-293G, pack of 25

Description

Regenerated cellulose membrane filters are reinforced with nonwoven cellulose. The membranes are mainly used for particle removal from solvents.

Color

White

Material

Regenerated cellulose, reinforced with non-woven cellulose

Reaction to Water

Hydrophilic

Pore Size (Nominal)

0.45 µm

Structure

Asymmetrically reinforced membrane

Applications and Features

Typical Applications

Ultracleaning and de-gassing solvents and mobile phases for HPLC. Particle removal from solvents.

Special Features

- Excellent chemical compatibility
- Superior thermal resistance

Technical Advantages

- Compatible with almost all solvents.
- Autoclavable at up to 134°C

Typical Performance

Adsorption, Non-specific

Bovine serum albumin, < 10 µg/cm²

Bubble Point with Water (DIN 58355)

2.9 bar | ~ 42 psi

Chemical Compatibility

Compatible with aqueous solutions (pH 3-12) and organic solvents.

Extractables with Water

< 1%

Flow Rate for Water per cm² (acc. to DIN 58355)

30 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods

Autoclaving at up to 134°C (dry heat recommended), dry heat at 180°C for 2 hours, ETO sterilization, γ-irradiation (25 kGy)

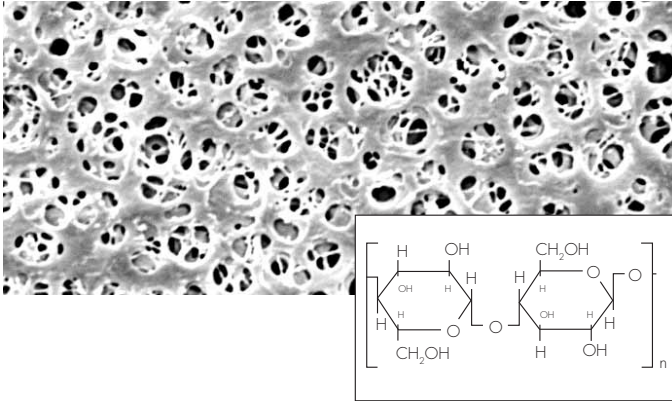
Thermal Resistance

200°C max.

Thickness (DIN 53105)

Approx. 170 µm

3.5 Regenerated Cellulose Membrane Type 18407, 0.2 μm



Order Numbers

13 mm diameter:
18407-013N, pack of 100

25 mm diameter:
18407-025N, pack of 100

47 mm diameter:
18407-047N, pack of 100

50 mm diameter:
18407-050N, pack of 100

142 mm diameter:
18407-142 G, pack of 25
18407-142 N, pack of 100

293 mm diameter:
18407-293 G, pack of 25

Description

Regenerated cellulose membrane filters are reinforced with nonwoven cellulose. They are mainly used for particle removal from solvents.

Color

White

Material

Regenerated cellulose, reinforced with non-woven cellulose

Reaction to Water

Hydrophilic

Pore Size (Nominal)

0.2 μm

Structure

Asymmetrically reinforced membrane

Applications and Features

Typical Applications

Filtration of organic solvents

Special Features

- Excellent chemical compatibility
- Superior thermal resistance

Technical Advantages

- Compatible with almost all solvents.
- Autoclavable at up to 134°C

Typical Performance

Adsorption, Non-specific

Bovine serum albumin, < 10 $\mu\text{g}/\text{cm}^2$

Bubble Point with Water (acc. to DIN 58355)

4.4 bar | \sim 64 psi

Chemical Compatibility

Compatible with aqueous solutions (pH 3–12) and organic solvents.

Extractables with Water

< 1%

Flow Rate for Water per cm^2 (DIN 58355)

15 ml/min at $\Delta p = 1$ bar | \sim 15 psi

Sterilization Methods

Autoclaving at up to 134°C, dry heat at 180°C for 2 hours, ETO sterilization, γ -irradiation (25 kGy)

Sterilizing Filtration

No absolute sterile filtration
Retention of 10^5 Brevundimonas diminuta/cm² filter area

Thermal Resistance

200°C max.

Thickness (DIN 53105)

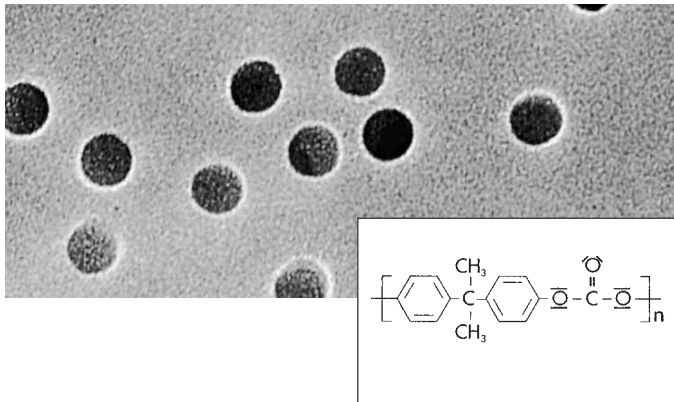
Approx. 170 μm

Retentive Capacity

Retention of Brevundimonas diminuta, ATCC 19146 test organisms ($10^5/\text{cm}^2$ filter area). Must not be used for sterile filtration.

3.6 Polycarbonate Membranes

Type 23006, 0.4 μm



Order Numbers

25 mm diameter:
23006-025N, pack of 100

47 mm diameter:
23006-047N, pack of 100

Description

Polycarbonate Track-Etch membranes are manufactured from high grade polycarbonate film using track-etch technology. They retain particles on their surfaces. Their capillary pore structure is uniform and precise with a narrow pore size distribution.

Color

White

Material

Polycarbonate

Reaction to Water

Hydrophilic

Pore Size (Nominal)

0.4 μm

Structure

Symmetric

Applications and Features

Typical Applications

Particulate analysis, epifluorescence microscopy, fluid clarification, cytology, cell biology, bioassays, water microbiology, environmental analysis.

Special Features

- Porosity < 15%
- Uniform capillary structure

Technical Advantages

- Excellent surface capture
- High sample visibility
- Resistant at pH 4-8

Typical Performance

Adsorption, Non-specific

BSA < 5 $\mu\text{g}/\text{cm}^2$

Bubble Point (DIN 58355)

2.5 bar | ~ 36 psi minimum

Burst Pressure

0.7 bar | 10 psi

Chemical Compatibility

See table page 41

Flow Rate for Water per cm^2 (DIN 58355)

70 ml/min at $\Delta p = 1$ bar | ~ 15 psi

Sterilization Methods

Autoclaving at up to 121°C

Thermal Resistance

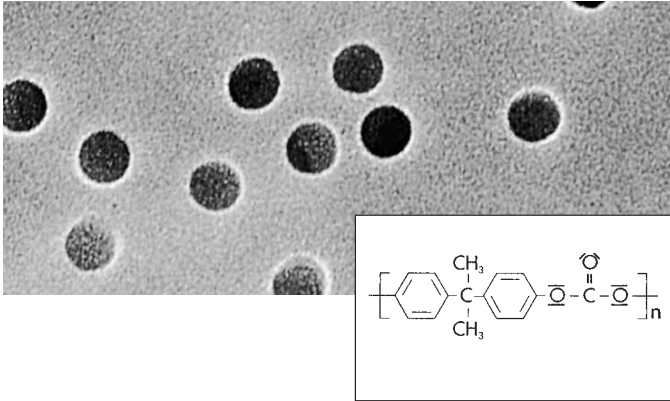
140°C max.

Thickness (DIN 53105)

Approx. 6-11 μm

3.6 Polycarbonate Membranes

Type 23007, 0.2 μm



Order Numbers

25 mm diameter:
23007-025N, pack of 100

47 mm diameter:
23007-047N, pack of 100

Description

Polycarbonate Track-Etch membranes are manufactured from high-grade polycarbonate film using track-etch technology. They retain particles on their surfaces. Their capillary pore structure is uniform and precise, with a narrow pore size distribution.

Color
White

Material
Polycarbonate

Reaction to Water
Hydrophilic

Pore Size (Nominal)
0.2 μm

Structure
Symmetric

Applications and Features

Typical Applications

Particulate analysis, epifluorescence microscopy, fluid clarification, cytology, cell biology, bioassays, water microbiology, environmental analysis.

Special Features

- Porosity < 15%
- Uniform capillary structure

Technical Advantages

- Excellent surface capture
- High sample visibility
- Resistant pH 4–8

Typical Performance

Adsorption, Non-specific
BSA < 5 $\mu\text{g}/\text{cm}^2$

Bubble Point (DIN 58355)
4.8 bar | ~ 70 psi minimum

Burst Pressure
0.7 bar | 10 psi

Chemical Compatibility
See table page 41

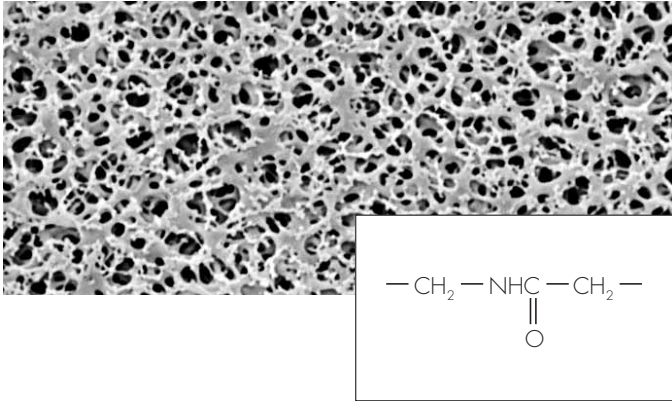
Flow Rate for Water per cm^2 (DIN 58355)
20 ml/min at $\Delta p = 1$ bar | ~15 psi

Sterilization Methods
Autoclaving at up to 121°C

Thermal Resistance
140°C max.

Thickness (DIN 53105)
Approx. 6–11 μm

3.7 Polyamide Membrane Type 25006, 0.45 µm



Tests According to USP Standards

Absence of pyrogens (endotoxin content)

Passed

Biological testing (Plastic Class VI)

Passed

Extractables

Passed test after standard flushing

Particle release

Passed

Description

Polyamide membrane filters are chemically resistant to alkaline solutions and organic solvents. They are therefore recommended for particle removing filtration of water, aqueous solutions and solvents for analytical determinations such as HPLC, as well as for the filtration of these liquids.

Color

White

Material

Polyamide

Reaction to Water

Hydrophilic

Pore Size (Nominal)

0.45 µm

Structure

Symmetric membrane

Applications and Features

Typical Applications

Microbe-retentive, particle-reducing filtration of water, alkaline solutions and solvents.

Special Features

- Excellent chemical compatibility
- Superior thermal resistance

Technical Advantages

- Wide range of use.
- Autoclavable at 121°C or 134°C

Typical Performance

Adsorption; non-specific

~ 50 µg/cm² for bovine serum albumin

Bubble Point with Water (Sartocheck)

min. 2.3 bar | ~ 3 psi

Burst Pressure

0.2 bar | ~ 4.35 psi

Chemical Compatibility

Compatible with several bases and almost all organic solvents, pH range 3-14.

Flow Rate for Water per cm² (acc. to DIN 58355)

35 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods

Autoclaving at 121°C or 134°C.

Retentive Capacity

100% retention of Serratia marcescens test organisms (10⁷/cm² filter area)

Thermal Resistance

Max. continuous operating temperature in water: 100°C.

Thickness (acc. to DIN 53105)

Approx. 115 µm

Order Numbers

13 mm diameter:
25006-013N, pack of 100

25 mm diameter:
25006-025N, pack of 100

47 mm diameter:
25006-047N, pack of 100

50 mm diameter:
25006-050G, pack of 25

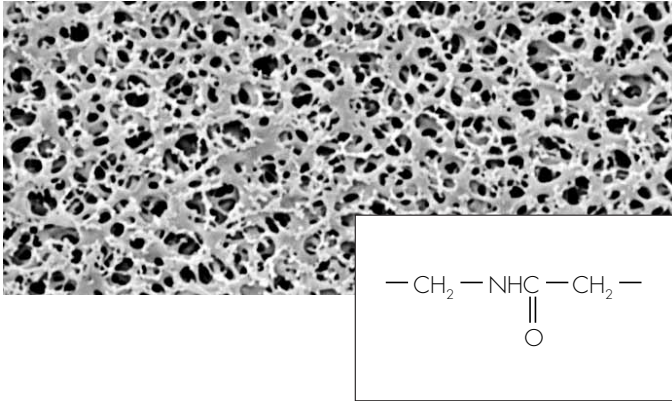
90 mm diameter:
25006-090G, pack of 25

142 mm diameter:
25006-142N, pack of 100

293 mm diameter:
25006-293N, pack of 100

3.7 Polyamide Membranes

Type 25007, 0.2 µm



Description

Polyamide membrane filters are chemically resistant to alkaline solutions and organic solvents. They are therefore recommended for particle removing filtration of water, aqueous solutions and solvents for analytical determinations such as HPLC.

Color
White

Material
Polyamide

Reaction to Water
Hydrophilic

Pore Size (Nominal)
0.2 µm

Structure
Symmetric

Applications and Features

Typical Applications

Sterile filtration of water, alkaline solutions and solvents.

Special Features

- Excellent chemical compatibility
- Superior thermal resistance
- Validated using *Brevundimonas diminuta*

Technical Advantages

- Wide range of use
- Autoclavable at 121°C or 134°C
- Reliable sterile filtration

Typical Performance

Adsorption, Non-specific
~ 50 µg/cm² for bovine serum albumin

Bubble Point with Water (Sartocheck)
3.2 bar | ~ 46 psi

Burst Pressure
0.2 bar | ~ 3 psi

Chemical Compatibility
Compatible with several bases and almost all organic solvents, pH range 3–14.

Flow Rate for Water per cm² (DIN 58355)
15 ml/min at Δp = 1 bar | ~ 15 psi

Sterilization Methods
Autoclaving at 121°C or 134°C.

Sterilizing Filtration
Validated with the Bacteria Challenge Test

Thermal Resistance
Max. continuous operating temperature in water: 100°C.

Thickness (DIN 53105)
Approx. 115 µm

Tests According to USP Standards

Absence of Pyrogens (Endotoxin Content)
Passed

Biological Testing (Plastic Class VI)
Passed

Extractables
Passed test after standard flushing

Particle Release
Passed

Retentive Capacity
100% retention of *Brevundimonas diminuta*, ATCC 19146 test organisms (10⁷/cm² filter area)

Order Numbers

13 mm diameter:
25007-013N, pack of 100

25 mm diameter:
25007-025N, pack of 100

47 mm diameter:
25007-047N, pack of 100

90 mm diameter:
25007-090G, pack of 25

142 mm diameter:
25007-142N, pack of 100

293 mm diameter:
25007-293N, pack of 100

4. Test Methods and Technical Information

4.1 Information on Sterilization

Sartorius Stedim Biotech membrane filters can be sterilized by different methods, which apply to the following membrane types:

111xx	Cellulose acetate
113xx	Cellulose nitrate
184xx	Regenerated cellulose, reinforced
250xx	Polyamide
154xx	PES
118xx	PTFE

4.1.1 Autoclaving

Membrane type	Temperature range (°C)	Pressure range (bar)	Time (min)	Condition
111xx	121–134	1–2	30–60	Wet
184xx	121–134	1–2	30–60	Wet
250xx	121–134	1–2	30–60	Wet
113xx	121	1	30–60	Wet
154xx	121–134	1–2	30–60	Wet

Note:

The above-mentioned membrane types should be wetted with water and placed in a filter holder before they are autoclaved. It is also necessary to assure that the membrane filter remains wetted throughout the autoclaving cycle and cooling process so that no post-vacuum is generated.

When a dry filter is autoclaved, constriction of the pore structure can result in reduction of the flow rate.

However, this does not adversely affect the microbial retention capacity.

Warning!

The temperature for cellulose nitrate membranes must not exceed 121°C because this could cause disintegration of the membrane.

Membrane type	Temperature range (°C)	Pressure range (bar)	Time (min)	Condition
118xx	121–134	1–2	30–60	Wet or dry

4.1.2 Steam Sterilization

For reliable sterilization of 111xx cellulose acetate membranes by in-line steaming, the steam pressure at 121°C must be 1 bar at the outlet of the filter holder.

This requires an inlet pressure of 1.2 bar – 1.3 bar, corresponding to a differential pressure of 0.2 – 0.3 bar.

Steam sterilize the membrane filter for 30 minutes after the maximum temperature has been reached.

4.1.3 Sterilization by Dry Heat

Dry heat is only suitable for 111xx cellulose acetate membranes at 180°C maximum for 30 minutes or 160°C for 180 minutes.

This method can only be used with filter holders that are specified to be able to withstand these temperatures.

Warning!

This method may not be used for 113xx cellulose nitrate membranes.

4.1.4 Sterilization with Ethylene Oxide

The following membrane filters can be sterilized with ethylene oxide:

111xx	Cellulose acetate
113xx	Cellulose nitrate
184xx	Regenerated cellulose, reinforced
250xx	Polyamide
154xx	PES
118xx	PTFE

4.1.5 Sterilization by γ -Radiation

The following membrane filters can be sterilized by γ -radiation (e.g. with 25kGy):

111xx	Cellulose acetate
113xx	Cellulose nitrate
184xx	Regenerated cellulose, reinforced
154xx	PES

γ -Radiation is not suitable for 25006/2007 Polyamide and 118xx PTFE material because the input energy could cause the membrane to disintegrate.

4.1.6 Sterilization by Chemical Disinfection

25 hours in 3% aqueous formaldehyde.

4.1.7 Ready-to-use Filters (Pre-Sterilized)

The applied sterilization method for the respective membrane products has been validated.

4.2 Test Methods

4.2.1 Bubble Point

The Bubble Point method is used to detect the largest pore in a membrane filter. The membrane is wetted and placed into a filter holder. Pressure is applied onto the membrane.

The Bubble Point is reached when air passes through the largest pores. The test is performed according to DIN 58355.

Note:

A certain quantity of air passes the membrane before the Bubble Point is reached. This passage of air is caused by diffusion. The rate of diffusion is increased by increasing the pressure. The Bubble Point is dependent on the medium used to wet the membrane.

4.2.2 Thickness

The thickness is measured with a gauge. The test is performed according to DIN 53105.

4.2.3 Flow Rate Water|Ethanol

A filter with a defined area is placed into a filter holder. A defined volume of medium is filtered through the membrane. Time is taken when the medium has been completely filtered through the membrane. The flow rate (ml/min bar cm²) is calculated from the test results. The test is performed according to DIN 58355.

4.2.4 Extractables with Water|Ethanol

A defined amount of membrane is extracted in a defined amount of water or alcohol.

The difference in weight before and after the extraction is measured. The loss of weight in percentage is calculated based on the results.

4.2.5 Burst Pressure

Air pressure is applied onto wet membrane without using a support. The pressure is recorded when the membrane bursts.

4.2.6 Air Flow

The amount of air which passes through the membrane at a specified pressure difference is measured. The flow rate is calculated from the test results. The test is performed according to ASTM D737, DIN 53'887, ISO 9'237.

4.2.7 Protein Binding

The membrane is immersed in a BSA solution until it is saturated.
The pH is 7.0, the buffer is 0.05 m KPi.
The excess BSA which is not bound is washed off with buffer. The BSA bound to the membrane is measured with BCA reagent.

Note:

The level of adsorption is dependent on the following variables:

- The test method
- The kind of membrane material and the kind of protein
- The environment (pH, salt concentration.)
- The total inner surface of the membrane sample (i.e. the pore size)

4.2.8 Bacteria Challenge Test

Establishing a correlation between bacterial retention of a sterilizing-grade filter and a non-destructive integrity test is decisive for determining the reliability of a sterile filtration process.

According to the Health Industry Manufacturers Association's (HIMA) regulations ASTM F 838-83 and DIN 58355, a sterilizing grade filter should produce a sterile filtrate when challenged with a minimum concentration of 10^7 *Brevundimonas diminuta* (ATCC 19146) organism/cm² of filter surface.

The FDA "Guidelines on Sterile Drug Products Produced by Aseptic Processing," June 1987 states:

"After a filtration process is properly validated for a given product, process and filter, it is important to assure that identical filter replacements (membrane or cartridge) used in production runs will perform in the same manner. One way of achieving this is to correlate filter performance data with filter integrity testing data.

Normally, integrity testing of the filter is performed after the filter unit is assembled and sterilized prior to use. More importantly, however, such testing should be conducted after the filter is used in order to detect any filter leaks or perforations that may have occurred during filtration."

4.2.9 Growth Promotion Test

The test is performed according to ISO 7704.

4.2.10 Sterility Test

The test is to confirm the sterility of pre-sterilized filters.

4.3 Chemical Compatibility**4.3.1 Test Method**

"The membrane is immersed for 24 h into the respective chemical. The Stability of the membrane is tested afterwards".

4.3.2 Results on Chemical Compatibility

Solvents	111	113	184	118	250	134	230	154
Acetone	-	-	•	•	-	•	○	-
Acetonitrile	?	?	•	•	-	?	?	•
Gasoline	•	•	•	•	•	•	•	•
Benzene	•	•	•	•	•	•	?	•
Benzyl alcohol	○	○	•	•	•	•	?	-
n-Butyl acetate	○	-	•	•	•	•	•	•
n-Butanol	•	•	•	•	•	•	•	•
Cellosolve	•	-	•	•	?	•	-	•
Chloroform	-	•	•	•	•	•	-	-
Cyclohexane	○	○	•	•	?	•	•	-
Cyclohexanone	-	-	•	•	•	•	?	?
Diethylacetamide	-	-	•	•	•	•	?	?
Diethyl ether	•	-	•	•	•	•	•	?
Dimethyl formamide	-	-	○	•	○	•	-	?
Dimethylsulfoxide	-	-	•	•	•	•	-	-
Dioxane	-	-	•	•	•	•	-	•
Ethanol, 98%	•	○	•	•	•	•	•	•
Ethyl acetate	-	-	•	•	•	•	?	-
Ethylene glycol	•	○	•	•	?	•	•	•
Formamide	?	?	?	•	?	•	-	?
Glycerin	•	•	•	•	•	•	•	•
n-Heptane	•	•	•	•	?	•	?	?
n-Hexane	•	•	•	•	•	•	•	?
Isobutanol	○	○	•	•	•	•	•	?
Isopropanol	•	○	•	•	•	•	•	•
Isopropyl acetate	○	-	•	•	?	•	?	•
Methanol, 98%	•	-	•	•	?	•	•	•
Methyl acetate	-	-	•	•	•	•	?	-
Methylene chloride	-	○	•	•	•	•	-	-
Methyl ethyl ketone	-	-	•	•	•	•	?	-
Methyl isobutyl ketone	•	-	•	•	•	•	?	?
Monochlorobenzene	•	•	•	•	•	•	-	?
Nitrobenzene	•	○	•	•	•	•	-	?
n-Pentane	•	•	•	•	•	•	•	?
Perchloroethylene	•	•	•	•	•	•	•	?
Pyridine	-	-	•	•	•	•	-	-
Carbon tetrachloride	○	•	•	•	•	•	?	•
Tetrahydrofuran	-	-	•	•	•	•	-	-
Toluene	•	•	•	•	•	•	?	•
Trichloroethane	○	•	•	•	?	•	?	?
Trichloroethylene	•	•	•	•	•	•	-	•
Xylene	•	•	•	•	•	•	•	•
Acids								
Acetic acid, 25%	•	•	•	•	○	?	○	•
Acetic acid, 96%	-	-	•	•	-	?	?	•
Hydrofluoric acid, 25%	•	○	○	•	-	?	•	?
Hydrofluoric acid, 50%	•	○	-	•	-	?	•	?
Perchloric acid, 25%	-	○	○	•	-	?	?	?
Phosphoric acid, 25%	•	○	○	•	-	?	?	?
Phosphoric acid, 85%	○	○	○	•	-	?	-	?
Nitric acid, 25%	-	○	-	•	-	?	•	•
Nitric acid, 65%	-	-	-	•	-	?	•	•
Hydrochloric acid, 25%	-	○	-	•	-	?	•	•
Hydrochloric acid, 37%	-	-	-	•	-	?	•	•
Sulfuric acid, 25%	-	○	○	•	-	•	?	•
Sulfuric acid, 98%	-	-	-	•	-	?	-	?
Trichloroacetic acid, 25%	-	○	•	•	-	?	?	?
Bases								
Ammonium, 1N	•	•	○	•	•	•	-	•
Ammonium hydroxide, 25%	-	○	-	○	•	○	-	•
Potassium hydroxide, 32%	-	-	○	○	○	○	-	•
Sodium hydroxide, 32%	-	-	○	•	○	○	-	•
Sodium, 1N	○	-	○	•	•	•	-	•
Aqueous solutions								
Formalin, 30%	○	•	○	•	○	•	•	•
Sodium hypochlorite, 5%	•	○	•	•	○	•	?	?
Hydrogen peroxide, 35%	•	•	○	•	○	?	?	?

Key to symbols

• = compatible

○ = limited compatibility

- = not compatible

? = not tested

E = compatible after replacing silicone O-ring with an EPDM O-ring

V = compatible after replacing the silicone O-ring with a Viton O-ring

4.4 Test Methods According to USP

The tests for particle release and extractable substances of the flat filters mentioned below are performed by dynamic extraction using a 293-mm diameter sample membrane. This method is the best way with actual filtration applications to determine contents of extractable substances and particles present in subsequent filtrate volumes. The samples for all tests are taken after 1.2 and 6 liters flush volume.

According to the specifications given in section "Sterile Water for Injection" of the current USP, the membrane filter samples listed below were analyzed for particulate matter, oxidizable substances, pH and conductivity, ammonia, sulfate and chloride. The tests were performed according to the descriptions given in the current USP. The test results obtained were compared with the current USP specifications in section "Sterile Water for Injection".

4.4.1 Particle Content in the Filtrate

4.4.1.1 Test Method

A membrane sample was briefly wetted with water for injection, placed into a filter holder and flushed with water for injection; filtrate samples were taken after 1.2 and 6 l flush volume. The results were evaluated according to the specification of the current USP section "Sterile Water for Injection"

4.4.2 Extractable Substances

To ensure that a medium has undergone a filtration unchanged a pre-rinsing of the membrane is required for certain types of membrane.

The purpose of the extractable tests is to determine the required pre-rinsing volume.

4.4.2.1 Test Methods

pH and Conductivity

Conductivity and the pH value of the samples were measured using appropriately calibrated pH meters and conductivity meters according to current USP regulations.

Determination of Chloride

Add 5 drops of nitric acid and 1 ml of silver nitrate to a 20 ml sample of the flushed water and mixed gently. The test is passed if the turbidity formed within 10 minutes is below the control reagent consisting of 20 ml of high purity water containing 10 µg of chloride .

Determination of Sulfate

Add 1 ml of barium chloride to a 100 ml sample of the flushed water. The test is passed if no turbidity forms .

Determination of Ammonia

Add 2 ml of alkaline mercuric-potassium iodide to a 100 ml sample of flushed water. The test is passed if any yellow color produced immediately is not darker than that of a control containing 30 µg of NH₃ added is passed in high purity water.

Determination of Oxidizable Substances

Add 2N sulfuric acid to the 100 ml of flushed water 10 ml and heat. Then 0.2 ml of 0.1 N potassium permanganate add and boild for 5 minutes. If a precipitation forms, it is cooled to room temperature. If the precipitate retains its color after cooling to room temperature, both test sample and test filter meet the USP specification for oxidizable substances.

5. Validation Guide

5.1 Bacteria Challenge test

Establishing a correlation between bacterial retention of a sterilizing grade filter and a non-destructive integrity test is decisive for the reliability of a sterile filtration process.

According to Health Industry Manufacturers Association (HIMA) regulations ASTM F 838-83 and DIN 58355, a sterilizing grade filter should produce a sterile filtrate when challenged with a minimum concentration of 10^7 *Brevundimonas diminuta* (ATCC 19146) organisms/cm² of filter surface.

The FDA "Guidelines on Sterile Drug Products Produced by Aseptic Processing", June 1987 states:

"After a filtration process is properly validated for a given product, process and filter, it is important to assure that identical filter replacements (membrane or cartridge) used in production runs will perform in the same manner.

One way of achieving this is to correlate filter performance data with filter integrity testing data.

Normally, integrity testing of the filter is performed after the filter unit is assembled and sterilized prior to use. More importantly, however, such testing should be conducted after the filter is used in order to detect any filter leaks or perforations that may have occurred during filtration."

5.1.1 Correlation of Bubblepoint with test

5.1.1.1 Test method

The test has been performed with 0.2 µm filters. Several samples of each membrane type were selected and underwent a bacterial challenge test according to ASTM F 838-83 and DIN 58355.

Test organism: *Brevundimonas diminuta* (ATCC 19146)

Challenge: $\geq 10^7$ organism/cm² effective filter area

Before performing the bacteria challenge test, the Bubble Point of the membrane filters were measured with a Sartocheck® as follows:

Test class:	small systems
Recognition point	
Bubble Point:	50 ml/min
Diameter of the filter:	142 mm

Bubble Point tests performed on original membrane material without undergoing any sterilization method.

5.1.1.2 Results

Membrane type: 11107

Membrane lot number	Bubble Point (bar)	BC test results
9804123	2.11	Non-sterile
0100413	2.19	Non-sterile
0400393	2.24	Non-sterile
9901203	2.54	Non-sterile
0400393	2.56	sterile
0400393	2.76	sterile
0400393	2.88	sterile
0400393	2.90	sterile
0400393	2.94	sterile
0101673	3.23	sterile
0101153	3.28	sterile
0101713	3.29	sterile

Membrane type: 15407

Membrane sample	Bubble Point (bar), Sartocheck	BC test results
1	2.35	non sterile
2	2.7	sterile
3	2.75	non sterile
4	2.8	sterile
5	2.9	steril
6	3.0	steril
7	3.1	steril
8	3.2	steril
9	3.3	steril
10	3.4	steril
11	3.5	steril
12	3.6	steril

Membrane type: 25007

Membrane sample	Bubble Point (bar), Sartocheck	BC test results
1	3.00	non sterile
2	3.05	non sterile
3	3.1	non sterile
4	3.15	steril
5	3.2	steril
6	3.25	steril
7	3.3	steril
8	3.35	steril
9	3.4	steril
10	3.45	steril
11	3.5	steril
12	3.55	steril

The table 11107 shows that all filter with a Bubble Point between 2.11 – 2.54 bar give non-sterile filtrates.

Taking a safety factor into consideration the following statement can be given:

A filter tested with an automated integrity test system and which gives a Bubble Point of > 2.9 bar can be used as sterile grade filter.

5.1.2 Correlation Bubble Point (according to DIN 58355) to BC test

5.1.2.1 Test method

the test has been performed with 0,2 µm 11107 filters. Several sample were selected and underwent a bacterial challenge test according to ASTM F 838-83 and DIN 58355.

Test organism: Brevundimonas diminuta (ATCC 19146)

Challenge: ≥ 10⁷ organism/cm² effective filter area

Before performing the bacteria challenge test, the Bubble Point of the membrane filters were measured visually in accordance to DIN 58355 using RO-water as wetting liquid.

Pressure increase: 14 s/bar

wetting volume: 20 ml RO-water

Diameter of the filter: 142 mm

Tests performed on original membrane material without undergoing any sterilization method.

5.1.2.2 Results

Membrane type: 11107

Membrane lot number	Bubble Point (bar, according DIN 58355)	BC test results
9804123	2.45	Non-sterile
0100413	2.55	Non-sterile
0400393	2.55	Non-sterile
9901203	3.05	Non-sterile
0400393	3.1	sterile
0400393	3.2	sterile
0400393	3.35	sterile
0400393	3.45	sterile
0400393	3.7	sterile
0101673	3.23	sterile
0101153	3.8	sterile
0101713	3.8	sterile

Table 11107a shows that all tested 11107 cellulose acetate membrane filters with a minimum Bubble Point of 3,1 bar retain the test organism Brevundimonas diminuta completely. Taking a safety factor into consideration the following statement is valid:

"A filter tested with a test system according to DIN 58355 and which gives a Bubble Point of ≥ 3,3 bar can be used as sterile grade filter."

Membrane type: 11407

Lot number	Bubble Point (bar, according DIN 58355)	Result
9702183	3.0	Non-sterile
9902803	3.5	Non-sterile
9902803	3.9	Sterile
0101663	4.5	Sterile
0101783	5.0	Sterile

Table 11407 shows that all tested 11407 cellulose nitrate membrane filters with a nominal pore size of 0,2 µm and a Bubble Point of 3.9 bar retain the test organism Brevundimonas diminuta completely.

Taking a safety factor into consideration a 11407 filter with a minimum Bubble Point of 4,0 bar (according to DIN 58355) can be used as a sterile grade filter.

Membrane type: 11807

Membrane lot number	Bubble Point (bar, according DIN 58355) measured with IPA/water	BC test results
05021900	1.2	sterile
05021900	1.25	sterile
05021900	1.3	sterile
05001600	1.35	sterile
04015600	1.4	sterile
06003600	1.5	sterile
05008400	1.55	sterile
06003600	1.6	sterile

Membrane type 18407

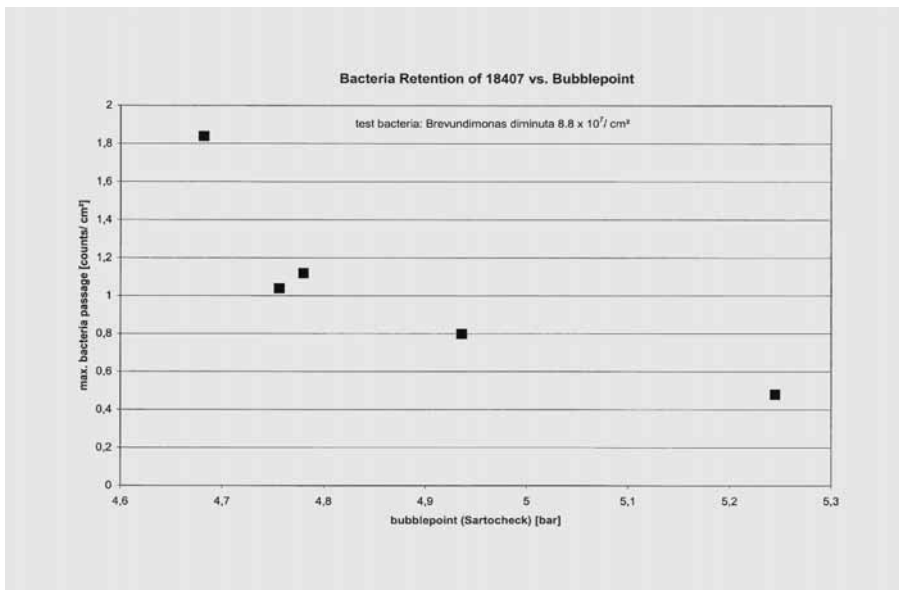


Table 18407 shows that the membrane material 18407 should not to be used as a sterile grade filter. This membrane only does have a retention rate of LRV 5.

General remark:

Due to the relatively small effective filtration area of a disc filter membrane the Bubble Point test is conducted to demonstrate the integrity of the membrane.

The air diffusion test can be used as additional indicator to help assess the integrity.

When doing so, it has to be considered that for small filter areas and with acceptable test times the diffusion volume is so low that it cannot be determined with sufficient accuracy. At long test times, the results are influenced significantly by non-constant test conditions

5.2 Testing According to USP

The tests for particle release and extractable substances of below mentioned flat filters are performed by dynamic extraction using a 293 mm diameter membrane sample. This method is corresponding the best way with actual filtration applications determining contents of extractable substances and particles present in subsequent filtrate volumes. The samples for all tests are taken after 1,2 and 6 liters flush volume.

According to the specifications given in section "Sterile Water for Injection" of the current USP, the below mentioned membrane filter samples are analyzed for Particulate Matter, Oxidizable Substances, pH and conductivity, Ammonia, Sulfate and Chloride. The tests are performed according to the descriptions given in the current USP. The test results obtained are compared the current USP specifications in section "Sterile Water for Injection"

5.2.1 Particle content in the filtrate

5.2.1.1 Test method

A membrane sample was shortly wetted with water for injection, put into a filter holder and flushed with water for injection, subsequent filtrate samples were taken after 1,2 and 6 l flush volume.

The results are compared to the specification of the current USP section "Sterile Water for Injection"

5.2.1.2 Results

11107

Sample	Limit 1 10 µm particle size Max 25 particle	Limit 2 25 µm particle size Max 3 particle
0101643	Passed	Passed
0101673	Passed	Passed
0101713	Passed	Passed

18407

Sample	Limit 1 10 µm particle size Max 25 particle	Limit 2 25 µm particle size Max 3 particle
0100993	Passed	Passed
0101243	Passed	Passed
0101543	Passed	Passed

5.2.2 Extractable Substances

To ensure that a medium is undergoing a filtration unchanged a pre-rinsing of the membrane is required for certain types of membrane.

The purpose of the extractable tests is to determine the required pre-rinsing volume.

5.2.2.1 Test methods

pH and Conductivity

Conductivity and the pH value of the samples were measured using appropriate calibrated pH meters and conductivity meters according to the current USP regulations.

Determination of Chloride

To a 20 ml sample of the flushed water 5 drops of nitric acid and 1 ml of silver nitrate are added and gently mixed. If the turbidity formed within 10 minutes is below the control reagent consisting of 20 ml of high purity water containing 10 µg of Chloride the test is passed.

Determination of Sulfate

To a 100 ml sample of the flushed water 1 ml of barium chloride is added. If no turbidity forms the test is passed.

Determination of Ammonia

To a 100 ml sample of flushed water 2 ml of alkaline mercuric-potassium iodide is added. If any yellow color produced immediately is not darker than that of a control containing 30 µg of added NH₃ in High Purity Water the test is passed.

Determination of Oxidizable Substances

To 100 ml of flushed water 10 ml of 2N sulfuric acid were added and heated. Than 0.2 ml of 0.1 N potassium permanganate were added and the solution was boiled for 5 minutes. If a precipitation forms, it is cooled to room temperature. If the precipitate remains its color after cooling to room temperature, the test sample and respectively the test filter meets the UPS specification for oxidizable substances.

5.2.2.2 Results

11107

Lots: 0101643, 0101673, 0101713

Analysis	Limit according the current USP	Rinse volume (l)	Result
Oxidizable Substances	Negative	0 – 1	Not passed
		1 – 2	Passed
		5 – 6	Passed
Conductivity [µS/cm]	See table pH/conductivity	0 – 1	Passed
		1 – 2	Passed
		5 – 6	Passed
pH	Between 5 – 7	0 – 1	Passed
		1 – 2	Passed
		5 – 6	Passed
Total solids	< 4 mg	0 – 1	Passed
		1 – 2	Passed
		5 – 6	Passed
Ammonia	Negative	0 – 1	Passed
		1 – 2	Passed
		5 – 6	Passed
Chloride	Negative	0 – 1	Passed
		1 – 2	Passed
		5 – 6	Passed
Sulfate	Negative	0 – 1	Passed
		1 – 2	Passed
		5 – 6	Passed

Conclusion: Before filtering the medium through a 11107 membrane a pre-rinsing volume of ≥ 1,0 l/100 cm² filter area is required.

18407

Lots: 0101243, 0101543

Analysis	Limit according the current USP	Rinse volume (l)	Result
Oxidizable Substances	Negative	0 – 1	Passed
		1 – 2	Passed
		5 – 6	Passed
Conductivity [µS/cm]	See table pH/conductivity	0 – 1	Passed
		1 – 2	Passed
		5 – 6	Passed
pH	Between 5 – 7	0 – 1	Passed
		1 – 2	Passed
		5 – 6	Passed
Total solids	< 4 mg	0 – 1	Passed
		1 – 2	Passed
		5 – 6	Passed
Ammonia	Negative	0 – 1	Passed
		1 – 2	Passed
		5 – 6	Passed
Chloride	Negative	0 – 1	Passed
		1 – 2	Passed
		5 – 6	Passed
Sulfate	Negative	0 – 1	Passed
		1 – 2	Passed
		5 – 6	Passed

Table pH/Conductivity

Remark:

The relationship between the pH value and the maximum allowable conductivity for "Sterile Water for Injection" according to the current USP is:

PH Value	Maximum Allowable conductivity [μ S]
5	4.7
5.1	4.1
5.2	3.6
5.3	3.3
5.4	3.0
5.5	2.8
5.6	2.6
5.7	2.5
5.8 – 6.1	2.4
6.2	2.5
6.3	2.4
6.4	2.3
6.5	2.2
6.6	2.1
6.7	2.6
6.8	3.1
6.9	3.8
7.0	4.6

5.2.3 Content of Endotoxins

Many pharmaceutical products are required to be free of pyrogens. Therefore filters must not contaminate the filtrate with bacterial endotoxins.

5.2.3.1 Test method

100 cm² of each below mentioned membrane type is shaken vigorously with 0,5 l of pyrogen-free water under non-pyrogenic conditions. The aqueous extract is tested with LAL reagent as specified in the USP 25 for the "Bacterial Endotoxins Test".

5.2.3.2 Results

Membrane Filter	Limit: Bacterial endotoxins $\leq 0,06$ EU/ml
11105	Passed
11106	Passed
11107	Passed
12303*	Passed
15406*	Passed
15407*	Passed
18406	Not applicable
18407	Not applicable

5.2.4.2 Results

Membrane type	Intraperitoneal	Intravenous	Intracutan	Implantative
11105	Passed	Passed	Passed	Passed
11106	Passed	Passed	Passed	Passed
11107	Passed	Passed	Passed	Passed
12303*	Passed	Passed	Passed	Passed
15406*	Passed	Passed	Passed	Passed
15407*	Passed	Passed	Passed	Passed
18406	Passed	Passed	Passed	Passed
18407	Passed	Passed	Passed	Passed
25006**	Passed	Passed	Passed	Passed
25007**	Passed	Passed	Passed	Passed

* measured in a Minisart

** measured in Cardrigris

5.2.5 Cytotoxicity test

5.2.5.1 Test method

The test has been conducted by an independent institute.

5.2.5.2 Results

Membrane type	Cytotoxicity
11105	Passed
11106	Passed
11107	Passed
12303*	Passed
15406*	Passed
15407*	Passed
18406	Passed
18407	Passed
25006**	Passed
25007**	Passed

* measured in a Minisart

** measured in a cardrige

None of the tested membrane filters released more than 0.06 EU/ml of bacterial endotoxins under given conditions for this test.

5.2.4 Biological Tests (Plastic Class VI)

The purpose of this test is to ensure that all Sartorius Stedim Biotech Membrane Filters are biosafe and meet the requirements of the current USP for Plastic Class VI

5.2.4.1 Test method

The test has been conducted by an independent institute.

Without any revision

In the interest of product or documentation improvement, Sartorius Stedim Biotech reserves the right to change the information included in the Validation Guide Micro Filters at any time. In case of a valid contract the customer will be informed in advance if a specification will be changed.

6. Application Matrix

	CN	11403	13903	11301	11342	11302	11303	11404	13004	11305	11304	11405	13905	13005	114H6	139H6	11306	11406	
Sterile filtration																			
Sterile filtration of aqueous solutions		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Sterile filtration of gases particle reduction of gases		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Sterile filtration of acids*		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Sterile filtration of bases*		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Sterile filtration of solvents*		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Particle Reduction specific test methods																			
Particle reduction of gases		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Particle reduction of strong acids*		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Particle reduction of strong bases*		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Particle reduction of solvents*		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Reduction of particles and/or microorganisms in aqueous solutions		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Prefiltration of aqueous solutions		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Prefiltration of aqueous solutions with a high particle load		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Cell retention		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Ultracleaning of aqueous solutions		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Residue analysis		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hybrid testing		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Liquid scintillation		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Sample pre treatment		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Microscopy																			
Test of organic halogens in water, waste water (AOX)																			
Clear filtration		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Microbiological testing																			
Microbiological examination on products that contain particles		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Detection of total count of bacteria		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Detection of total count of bacteria in solutions containing inhibitors		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Excellent growth conditions microbiological testing		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Legionella testing		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Testing for yeasts and moulds airborne yeasts and molds		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Microbiological testing of solutions containing inhibitors		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
High flow rate		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Sterility test of solutions including inhibitors		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Sterilization methods																			
Autoclavable at 121°C		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Autoclavable at 134°C		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Dry heat sterilization possible		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
ETO-sterilization		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
γ-irradiation		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Membrane properties																			
Low non specific binding		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
High non specific protein binding		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Gridded black		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Gridded green		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Gridded white		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Colour		W	W	W	W	W	W	W	B	W	W	W	W	B	W	W	W	W	
Hydrophobic edge		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hydrophobic		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hydrophilic		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Nominal pore size (µm)																			
0.1																			
0.2																			
0.45																			
0.65																			
0.8																			
1.2		●	●					●											
3																			
5																			
8																			

* Details see chemical compatibility

● = recommended use
 ● = might work
 ● = not for this application

W = white
 G = green
 B = black

По вопросам продаж и поддержки обращайтесь:
Астана+7(7172)727-132, Волгоград(844)278-03-48, Воронеж(473)204-51-73, Екатеринбург(343)384-55-89,
Казань(843)206-01-48, Краснодар(861)203-40-90, Красноярск(391)204-63-61, Москва(495)268-04-70,
Нижегород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,
Санкт-Петербург(812)309-46-40, Саратов(845)249-38-78, Уфа(347)229-48-12
sst@nt-rt.ru || sartorius.nt-rt.ru