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3M™ LifeASSURE™ BFS Series Technical Support Guide

Contents

I. Introduction

This guide contains technical and regulatory support information pertinent to the 3M™ LifeASSURE™ BFS Series. It contains information that supports the safety, efficacy, and regulatory compliance of filters in food and beverage filtration applications.

3M LifeASSURE BFS filters are used in critical process stages where microbial-rated filtration is required. 3M LifeASSURE BFS filters meet the FDA's definition of a sterilizing grade filter as described in the *Food and Drug Administration (FDA) Guideline on Sterile Drug Products Produced by Aseptic Processing, (June 1987)*. 3M LifeASSURE BFS filters are qualified for quantitative retention of *Brevundimonas diminuta (B. diminuta)* at a minimum challenge of 10^7 organisms/cm^2 of effective filter surface area. Bacteria challenge studies were conducted in accordance with ASTM method F838-05.

This Technical Guide has been prepared specifically for manufacturers requiring product documentation as part of their validation process. It includes the following information to support published performance claims:

- Cartridge construction
- Part Numbering System
- *B. diminuta* retention and correlation to non-destructive integrity testing
- Air flow vs. differential pressure at atmospheric and elevated pressures
- Thermal stress — repeat steam cycles, repeat autoclave cycles

In addition to product performance test results, the following safety and regulatory support information is provided:

- Article Information Sheet
- Food contact regulatory compliance

3M would be pleased to supply you with any additional information you require. Further information may be obtained by contacting: 3M Purification Inc. Applications Engineering team at:

3M Purification Inc.
3M Separation and Purification Sciences Division
400 Research Parkway
Meriden, CT 06450 U.S.A.
Phone (800) 243-6894
(203) 237-5541

II. Cartridge Construction

Membrane: 3M™ LifeASSURE™ BFS Series filters are made with a hydrophobic PTFE membrane.

Membrane inner and outer support layers: 3M LifeASSURE BFS Series PTFE membrane is pleated with a layer of polypropylene non-woven upstream support, and another layer downstream, to provide better flow access through the membrane pleats. Airflow is further enhanced by use of a second, polypropylene downstream flow distribution layer.

Cartridge hardware components: Inner core and outer cage are molded polypropylene. End cap adapters and plastic O-ring adapters are also polypropylene and contain a 316 stainless steel ring for structural stability. All cartridge filter components are assembled by thermal bonding.

Further details concerning 3M LifeASSURE BFS series filters specifications and operating conditions are provided as follows:

Table 1. 3M LifeASSURE BFS Series filter Materials of Construction

Filter configuration	Cartridge 10” to 30”
Membrane	PTFE
Membrane Support Layer	Polypropylene
Inner core, outer cage, capsule shell, end caps adapters and adapters	Polypropylene
Adapter Reinforcing Ring	Stainless Steel
Filtration Surface Area: ft^2 (m^2)	11 (1.02)*

*Per 10” element

III. Part Number Description

The table below provides the part numbering system for 3M LifeASSURE BFS filters.

Table 2. 3M LifeASSURE BFS Series Part Numbering System.

Grade design	Configuration	Height (Inches)	End Modification	O-ring material
BFS020	A	01-10	B-226 O-ring & spear	A-Silicone
		02-20	F-222 O-ring and flat cap	
		03-30		

IV. Product Operating Parameters

The table below provides operating parameters and specifications for 3M™ LifeASSURE™ BFS series filters.

Table 3. 3M LifeASSURE BFS Series Operating Parameters and Specifications.

Filter configuration	Cartridge 10” to 30”
Filter Rating	0.2 µm
Maximum Differential Pressure	
Forward Pressure	80 psid (5.5 bar) @ 77°F (25°C) 25 psid (1.7 bar) @ 176°F (80°C)
Reverse Pressure	65 psid (4.5 bar) @ 77°F (25°C)
Maximum Operating Temperature	176°F (80°C)
Integrity Parameters-Forward Flow Test-@ 16 psig (1.1 bar)**	
60%/40% (v/v) IPA/water @ 25°C and 1 atm: cc/min	≤35.5*
Minimum bubble point: psig (bar)***	16 (1.1)
Water Intrusion test--Maximum Allowable Flow at 40 psig (2.76 bar) @ 20°C and 1 atm: cc/min	0.59
In situ Steam Conditions:	Up to 293°F (145°C)

* not for continuous compressed gas service.

** NOTE: Wetting fluid should be maintained within +/- 2% v/v concentration and +/- 2°C temperature.

*** Wet with 60%/40% (v/v) IPA/Water.

V. Performance

A. Validation of Bacteria Retention and Correlation with Non-Destructive Integrity Tests

The validation of *B. diminuta* (ATCC 19146) retention for 3M™ LifeASSURE™ BFS filters were performed in accordance with American Society of Testing and Materials (ASTM) method F838-05. Using this test methodology, 3M LifeASSURE BFS series completely retained in excess of 1×10^7 CFU of *B. diminuta* per cm^2 of effective filter surface area.

The correlation between a non-destructive integrity test and assurance of microorganism retention is critical for filters used in sterile filtration applications. The 3M LifeASSURE BFS series validation study establishes the relationship between non-destructive integrity tests and bacteria retention and serves as the basis for establishing pre- and post-use integrity testing of production filters.

Correlation of the Forward Flow Integrity Test (25%/75% [v/v] TBA/Water wet) with Bacteria Retention:

Method:
3M LifeASSURE BFS series filters were taken from multiple production lots and steamed a minimum of five cycles. Cartridges were subjected to a forward flow integrity test and then challenge tested with *B. diminuta* in accordance with ASTM F838-05 to challenge levels in excess of 1×10^7 CFU/cm^2.

Each 10" cartridge was initially wetted with a 10-minute static soak of 25% tertiary butyl alcohol/75% water (v/v). Cartridges were then subjected to a forward flow integrity test using 16 psig of clean air. Forward flow rate (cc/min) at 20 °C and 1 atmosphere (1 atm) pressure in the forward flow direction was determined after allowing flow to stabilize. Cartridges were flushed to remove the residual alcohol prior to liquid challenge testing. Liquid challenge testing was then conducted using *B. diminuta* at challenge levels exceeding 1×10^7 CFU/cm^2 of filter area using ASTM methodology.

Results:
The test results shown in Table 4 demonstrate the correlation between the non-destructive Forward Flow Integrity Test and the complete retention of *B. diminuta*. 3M LifeASSURE BFS series with forward flow integrity values of less than or equal to 10.3 cc/min successfully passed the bacterial challenge validation test. A limit of 8.7 cc/min was established for routine integrity testing. Thus, any 25% tertiary butyl alcohol/75% water (v/v) wetted 3M LifeASSURE BFS series cartridge yielding a forward flow integrity value of less than or equal to 8.7 cc/min per 10" element at a 16 psi test pressure can be used with confidence.

Table 4. Correlation Test Results of the Forward Flow Integrity Test (25%/75% TBA/Water wet) with *B. diminuta* Retention for 3M™ LifeASSURE™ BFS Series 10" Cartridge Filters.

Serial Numbers	Forward Flow Integrity @ 20 °C in 25%TBA/75% H_2O (v/v) @ 16 psi (cc/min)	Sterile Effluent
02T003-0005	4.4	Yes
02T003-0013	4.6	Yes
02T003-0007, 02T003-0011	4.7	Yes
02T003-0023	5.0	Yes
02T008-0013	5.2	Yes
02T003-0001, 02T008-0033, 02T008-0004	5.6	Yes
02T003-0022, 02T008-0035	5.7	Yes
02T008-0040, 02T008-0008, 02T008-0007	5.8	Yes
02T003-0024, 02T008-0032, 02T008-0006	5.9	Yes
02T009-0010	6.2	Yes
02T009-0027	6.3	Yes
02T003-0012, 02T009-0022, 02T009-0001	6.7	Yes
02T009-0007	6.8	Yes
02T008-0031	6.9	Yes
02T003-0018	7.5	Yes
02T011-0015	7.9	Yes
02T011-0001	8.1	Yes
02T011-0029	9.5	Yes
02T011-0003	10.3	Yes
02T009-0009	10.5	No
02T011-0011	10.7	Yes
02T008-0037	12.7	No
02T009-0016	13.1	No
02T009-0011	13.9	No
02T008-0046	15.3	No
02T003-0008	16.3	No
02T011-0009	16.7	No
02T011-0019	18.2	Yes
02T011-0025	19.1	Yes
02T011-0007	20.3	No
02T003-0006	21.3	No
02T011-0013	21.8	Yes
02T008-0044	26.9	No
02T008-0016	45.0	No
02T008-0027	77.3	No

B. Correlation of the 25%/75% TBS/H_2O Forward Flow Integrity Test with 60%/40% IPA/ H_2O and 70%/30% IPA/ H_2O

Method:

3M™ LifeASSURE™ BFS Series filters are constructed with a hydrophobic PTFE membrane that requires a low surface tension fluid to thoroughly wet the membrane prior to performing an integrity test. 25%/75% TBA/H_2O (v/v) at a temperature of 20°C was used as the wetting fluid to measure the forward flow of production cartridges prior to bacteria challenge. The correlation of 25%/75% TBA/H_2O forward flow integrity test results with *B. diminuta* retention and establishment of integrity test limits is shown in Table 4. Other wetting fluids such as 60%/40% IPA/H_2O or 70%/30% IPA/H_2O (v/v) can also be used for integrity testing. In order to establish integrity test limits for these fluids, a correlation to the limits determined for 25%/75% TBA/H_2O can be determined by obtaining the ratio of the forward flow integrity test values between these fluids. The ratio of test values between two fluids is dependent on the diffusion constant and the solubility coefficient of the test gas in these fluids[1].

Forward flow integrity tests were performed on a series of 10" 3M LifeASSURE BFS cartridge filters from three different production lots. Filter integrity test results were generated using 60%/40% IPA/H_2O and 70%/30% IPA/H_2O as the wetting fluid and compared to the same cartridges wet with 25%/75% TBA/H_2O. The membrane bubble point variation for the membrane wet with the three fluids was not significant, therefore all forward flow testing was conducted at 16 psi independently of the wetting fluid. A ratio was calculated between the integrity test values obtained with these wetting fluids and the integrity test values obtained with 25%/75% TBA/H_2O.

The ratio was then used to calculate the maximum forward flow integrity test specification for each wetting solution based on the forward flow specification for the cartridge wet in 25%/75% TBA/H_2O. The IPA/H_2O based forward flow integrity test specifications for each wetting solution can be related to the bacterial retention correlation results of the product integrity tested when wet with 25%/75% TBA/H_2O (see Table 4 on previous page).

[1] PDA Technical Report No.26 “Sterilizing Filtration of Liquids”, PDA Journal of Pharmaceutical Science and Technology, 52, S1 (1998).

Results:

The results presented in Table 5 are the forward flow integrity measurements and averages for three production lots of 10" 3M™ LifeASSURE™ BFS series filters wet in 25%/75% TBA/H_2O, 60%/40% IPA/H_2O, and 70%/30% IPA/H_2O. The forward flow integrity test limits for a 10" LifeASSURE BFS series cartridge filter can then be calculated by the equation:

$$DFL_{IPA} = DFL_{TBA} * (DF_{AVG\ IPA} / DF_{AVG\ TBA})$$

Where:

DFL_{IPA}= IPA-wetted Diffusive Flow Limit

DFL_{TBA}= TBA-wetted Diffusive Flow Limit=8.7 cc/min for 10" LifeASSURE BFS series filter.

$DFL_{AVG\ IPA}$= Average IPA-wetted Diffusive Flow

$DFL_{AVG\ TBA}$= Average A-wetted Diffusive Flow

$DFL_{60/40\ IPA/H2O}$= (8.7)*(25.7/6.3)=35.5 cc/min

$DFL_{70/30\ IPA/H2O}$= (8.7)*(39.1/6.3)=54.0 cc/min

Therefore, the forward flow specification for 10" 3M LifeASSURE BFS series filters wet with 60%/40% IPA/H_2O is 35.5 cc/min and 54.0 cc/min for 10" cartridges wet with 70%/30%/IPA/H_2O (v/v).

These 60%/40% IPA/H_2O and 70%/30% IPA/H_2O integrity test specifications can be used for 10" cartridges. Integrity test specifications for devices of different sizes have been normalized for appropriate effective filtration area and are specified in Table 3. Wetting fluid concentrations and temperatures should be maintained within +/- 2% v/v concentration and +/- 2 °C.

Table 5. Correlation of the 25%/75% TBA/H_2O Forward Flow Integrity Test with 60%/40% IPA/H_2O and 70%/30% IPA/H_2O Wetting Fluids for 3M™ LifeASSURE™ BFS Series 10" Cartridge Filters.

Lot #	Serial #	25%/75% TBA/H_2O @ 16 psi & 20 °C (cc/min)	60%/40% IPA/H_2O @ 16 psi & 25 °C (cc/min)	70%/30% IPA/H_2O @ 16 psi & 25 °C (cc/min)
02T003	0089	6.3	25.4	39.4
02T003	0090	6.7	29.3	43.4
02T003	0091	6.5	26.9	40.7
02T003	0094	6.1	22.2	33.9
02T003	0097	6.4	27.4	39.4
02T003	0098	6.2	28.7	42.6
02T003	0099	6.8	27.8	48.0
02T003	0100	7.3	31.4	48.1
02T008	0010	5.8	22.7	33.9
02T008	0017	5.2	21.1	33.5
02T008	0022	5.6	20.5	33.6
02T008	0029	5.9	22.6	33.8
02T008	0043	6.4	22.8	33.6
02T008	0045	6.3	25.4	37.2
03T020	0767	6.3	25.3	40.6
03T020	0775	6.2	23.0	37.2
03T020	0778	6.3	25.3	36.9
03T020	0792	7.0	26.6	40.3
03T020	0793	6.5	26.1	39.5
03T020	0804	6.2	25.3	38.1
03T020	0807	6.4	26.5	40.1
03T020	0818	6.5	26.3	41.3
03T020	0826	6.4	25.4	35.7
03T020	0827	6.4	25.5	41.9
03T020	0829	6.1	25.3	37.3
03T020	0830	6.5	27.1	40.2
03T020	0831	6.5	27.1	39.8
03T020	0834	6.5	27.7	40.8
03T020	0835	6.5	27.2	42.1
03T020	0842	6.4	27.1	39.9
	Average	6.3	25.7	39.1

C. Correlation of the Water Intrusion Integrity Test (WIT) with Bacteria Retention:

Method:
3M™ LifeASSURE™ BFS Series filters were taken from multiple production lots and steamed a minimum of five cycles. Cartridges were subjected to a water intrusion integrity test and then challenge tested with *B. diminuta* in accordance with ASTM F838-05 to challenge levels in excess of 1×10^7 CFU/cm^2.

Each fully dry 10" cartridge was installed into a filter housing that was then filled with 20 °C water on the upstream side of the cartridge filter. The filter assembly was then subjected to a water intrusion integrity test at 40 psig. The water intrusion value (ml/min) was determined using a 3M automated integrity test instrument. Cartridges were then wetted with alcohol and flushed to remove residual alcohol prior to liquid challenge testing. Liquid challenge testing was then conducted using *B. diminuta* at challenge levels exceeding 1×10^7 CFU/cm^2 of filter area using ASTM methodology.

Results:
The test results shown in Table 6 demonstrate the correlation between the Non-Destructive Water Intrusion Integrity Test and the complete retention of *B. diminuta*. 3M LifeASSURE BFS series filters with water intrusion values of less than or equal to 0.60 ml/min successfully passed the bacterial challenge validation test. A limit of 0.59 ml/min was established for routine integrity testing. Thus, any 3M LifeASSURE BFS series filter yielding a water intrusion value of less than or equal to 0.59 ml/min per 10" element at a 40 psig test pressure can be used with confidence.

Table 6. Correlation Test Results of the Water Intrusion Integrity Test (WIT) with *B. diminuta* Retention for 3M™ LifeASSURE™ BFS Series 10" Cartridge Filters.

Serial Number	WIT @ 40 psig (2.8 bar) @ 20 °C & 1 atm (cc/min)	Sterile Effluent
02T003-0005	0.3	Yes
02T003-0024	0.3	Yes
02T003-0022	0.3	Yes
02T003-0012	0.4	Yes
02T003-0018	0.4	Yes
02T008-0040	0.4	Yes
02T003-0013	0.4	Yes
02T009-0022	0.4	Yes
02T008-0032	0.4	Yes
02T009-0010	0.4	Yes
02T003-0001	0.4	Yes
02T003-0007	0.4	Yes
02T003-0011	0.4	Yes
02T008-0033	0.4	Yes
02T008-0035	0.4	Yes
02T009-0027	0.4	Yes
02T008-0004	0.4	Yes
02T003-0023	0.4	Yes
02T008-0008	0.4	Yes
02T008-0006	0.4	Yes
02T009-0001	0.4	Yes
02T009-0007	0.5	Yes
02T008-0013	0.5	Yes
02T008-0031	0.5	Yes
02T008-0007	0.5	Yes
02T011-0015	0.5	Yes
02T011-0001	0.5	Yes
02T011-0029	0.6	Yes
02T011-0003	0.6	Yes
02T011-0011	0.6	Yes
02T003-0008	0.6	No
02T009-0016	0.6	No
02T009-0009	0.7	No
02T008-0046	0.7	No
02T011-0013	0.8	Yes
02T008-0037	0.8	No
02T011-0019	0.8	Yes
02T011-0009	0.8	No
02T011-0025	0.8	Yes
02T011-0007	0.9	No
02T009-0011	0.9	No
02T008-0044	0.9	No
02T003-0006	1.3	No
02T008-0016	1.4	No
02T008-0027	2.3	No

D. Demonstration of Aerosol Bacteriophage Virus Retention

The demonstration of bacteriophage ΦX-174 (ATCC 13706-B1) retention for 3M™ LifeASSURE™ BFS Series filters was performed using an aerosolized challenge suspension of virus particles. An aerosol suspension of particles represents a typical challenge air filters receive as vent filters or in compressed gas filtration service.

Method:

A bacterial culture of *Esherichia coli (E. coli)* (ATCC 13706) at a concentration of 2 x 10^8–4 x 10^8 colony forming units (CFU) per mL was inoculated with the bacteriophage ΦX-174 stock culture (ATCC 13706-B1). Following incubation and complete *E. coli* lysis, the ΦX-174 phage culture was centrifuged and filtered through a sterilizing grade 0.2 µm filter. The stock culture of ΦX- 174 was kept at 2 °C–8 °C.

The test filters were steam sterilized at 121° C for 1 hour. After the filter cooled to room temperature, the filter was placed into the test apparatus and the challenge aerosol initiated.

The challenge was delivered and sampling through an all glass liquid impinger (AGLI) was conducted to ensure clearance of residual aerosol from the chamber. Control runs (no filter in the test assembly) were performed before the test samples to determine the number of viral particles being generated in the challenge aerosol. A post challenge forward flow integrity test was performed on each cartridge filter at test pressure of 16 psig (1.1 bar). All cartridges were found to be integral.

The challenge suspension was delivered through a Chicago nebulizer using a peristaltic pump. The concentration was adjusted to provide a consistent challenge of > 1 x 10^8 plaque forming units (PFU) per test sample. The aerosol droplets were generated in a glass aerosol chamber and drawn into four all-glass liquid impingers (AGLI) in parallel. Each AGLI contained 30 mL aliquots of sterile peptone water (PEPW) to collect the aerosol droplets. The total air flow through the test filter was maintained at 140 liters per minute (LPM). Four AGLIs were connected in parallel to sample the effluent air at a flow rate of 48 LPM.

The AGLI fluid was assayed by placing 4 mL aliquots of each sample into tubes containing 2 mL of soft “top agar” and 2-3 drops of *E. coli* culture. The contents were mixed and poured over the surface of “bottom agar” plates. Plates were incubated at 37° C ± 2° C for 6–18 hours.

The Viral Filtration Efficiencies (VFE) were calculated using the following equation:

$$VFE\% = \frac{(average\ plaques\ [control] - plaques\ [filter\ effluent]) \times 100}{average\ plaques\ [control]}$$

Filters were flushed twice with 4 liters 60%/40% (v/v) isopropyl alcohol/water. An air pressure of 16 psig (1.1 bar) was applied, and the forward flow rate was determined after 5 minutes stabilization.

Results:

One third of the effluent air was collected for quantification during testing; therefore, the plaque assay results for the controls and samples were converted to reflect the entire quantity of air passing through the test filter. The challenge level and filtration efficiencies of the samples are summarized in Tables 7 and 8.

Table 7. Bacteriophage ΦX-174* Virus Aerosol Retention Test Results (3M™ LifeASSURE™ BFS Series 10" filters).

Cartridge Identification	Total Challenge (PFU)	Total Effluent Recovery (PFU)	Virus Filtration Efficiency (VFE)	Log Reduction Value (LRV)
02T003-0095	4.8×10^8	none detected	> 99.9999998%	> 8.7
02T003-0102	5.1×10^8	none detected	> 99.9999998%	> 8.7
02T003-0111	5.1×10^8	none detected	> 99.9999998%	> 8.7
02T009-0035	4.8×10^8	none detected	> 99.9999998%	> 8.7
02T009-0040	4.5×10^8	none detected	> 99.9999998%	> 8.7
02T009-0041	4.5×10^8	none detected	> 99.9999998%	> 8.7
02T020-0008	4.9×10^8	none detected	> 99.9999998%	> 8.7
02T020-0091	5.8×10^8	none detected	> 99.9999998%	> 8.7
02T020-0093	5.8×10^8	none detected	> 99.9999998%	> 8.7

*Master culture concentration: 1.5×10^9 PFU/mL

Conclusions:

For 3M™ LifeASSURE™ BFS series 10" filters at a minimum challenge level of 4.5×10^8 PFU, no PFU was detected in the effluent of all nine 10" cartridges.

E. Summary of 3M LifeASSURE BFS Filter Integrity Test Parameters

Table 8. Summary of 3M LifeASSURE BFS Series Filter Integrity Test Parameters.

BFS020 Filter Type	Maximum Allowable Forward Flow (cc/min) 25%/75% (v/v) TBA/ H_2O @ 16 psig (1.1 bar) @ 20 °C and 1 atm	Maximum Allowable Forward Flow (cc/min) 60%/40% (v/v) IPA/ H_2O @ 16 psig (1.1 bar) @ 25 °C and 1 atm	Maximum Allowable Forward Flow (cc/min) 70%/30% (v/v) IPA/ H_2O @ 16 psig (1.1 bar) @ 25 °C and 1 atm	Water Intrusion Test Maximum Allowable Flow (ml/min) @ 40 psig (2.8 bar) @ 20 °C and 1 atm	Minimum Bubble Point psig (bar)*
30" cartridge	26.1	106.5	162.0	1.77	16 (1.1)
20" cartridge	17.4	71.0	108.0	1.18	16 (1.1)
10" cartridge	8.7	35.5	54.0	0.59	16 (1.1)

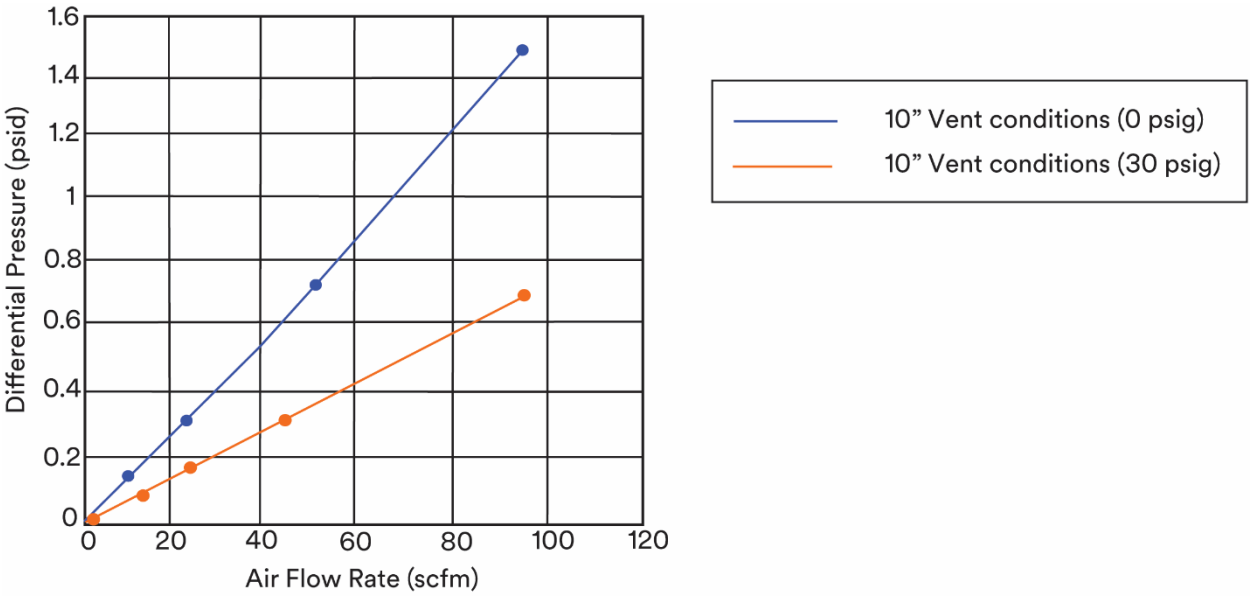
* Wet with 25%/75% (v/v) TBA/Water, 60%/40% (v/v) IPA/Water, or 70%/30% (v/v) IPA/Water

F. Air Flow Rate

Method:
3M™ LifeASSURE™ BFS filters were taken from multiple production lots for airflow performance testing.
Cartridges were assembled into a filter housing and the differential pressure across the filter assembly was measured while clean filtered air was directed through the housing at a range of controlled flow rates 10" cartridges tested utilized the 226 O-ring adapter. Differential pressures were measured for both vent (0 psig) and compressed gas (30 psig) conditions. Differential pressures were measured for the empty housing and were subtracted from the measured differential pressures at the appropriate flow rates.

Results:
The airflow graphs below serve to provide typical values for flow data and can be used for sizing filter systems using 3M LifeASSURE BFS series filters. Housing pressure losses should be added to filter pressure losses when determining system pressure loss. For additional assistance in sizing air filter assemblies, consult 3M Purification Inc. Sales.

Graphs 1. Summary of 3M LifeASSURE BFS Series Typical Airflow Rates.



G. Thermal Stress

Cartridge Steam Sterilization

3M™ LifeASSURE™ BFS Series filters are designed to perform in demanding process conditions. Materials of construction and cartridge design provide an extremely durable envelope that can be *in situ* steam sterilized (or autoclaved) repeatedly without loss of integrity.

Method:

3M LifeASSURE BFS series cartridges were taken from multiple production lots for repeat *in situ* steam sterilization performance. Dry cartridges were installed in filter housings and steam sterilized *in situ* at 145 ˚C for a total of 200 sterilization cycles (30 minutes per cycle). Between cycles, the filter housing temperature was allowed to drop below 100 ˚C. Cartridges were steamed in both the forward flow and reverse flow orientation. Cartridges were subjected to both the Water Intrusion Integrity Test at 40 psig test pressure as well as the Forward Flow Integrity Test method in 25%/75% TBA/H_2O tested at 16 psig test pressure.

Results:

The results shown in Table 9 demonstrate the robustness of the 3M LifeASSURE BFS series filters. Cartridges were shown to maintain acceptable integrity values and complete *B. diminuta* retention following 200 steam sterilization cycles. The 3M LifeASSURE BFS series filters should be considered equally resilient to autoclave sterilization.

Table 9. Integrity Test Results after Repeat Steam Sterilization Cycles at 145 °C for 3M™ LifeASSURE™ BFS Series 10" Cartridge Filters.

Serial Number	Steam Flow Direction	Integrity after 200 Steam Cycles		*B. diminuta* Retention (Sterile Effluent)
		WIT (ml/min)	FFIT @ 20 °C (cc/min)	
02T003-0012	Forward	0.35	6.7	Yes
02T003-0022	Forward	0.33	5.7	Yes
02T003-0024	Forward	0.31	5.9	Yes
02T008-0032	Forward	0.38	5.9	Yes
02T008-0033	Forward	0.39	5.6	Yes
02T008-0040	Forward	0.36	5.8	Yes
02T009-0033	Forward	0.47	6.8	Yes
02T009-0042	Forward	0.41	6.5	Yes
02T009-0044	Forward	0.35	5.6	Yes
02T003-0005	Reverse	0.29	4.4	Yes
02T003-0018	Reverse	0.36	7.5	Yes
02T008-0031	Reverse	0.48	6.9	Yes
02T008-0035	Reverse	0.41	5.7	Yes
02T009-0039	Reverse	0.46	6.2	Yes
02T009-0043	Reverse	0.42	6.7	Yes

WIT = Water Intrusion Test with 20 °C water tested at 40 psi.

FFIT = Forward Flow Integrity Test @ 20 °C and 1 atm wet with 25%/75% TBA/H_2O tested at 16 psi.

VI. Appendix A
EHSR

LifeASSURE™ BFS SERIES FILTER CARTRIDGES

This document provides basic information regarding various regulatory and industry standards relating to the product referenced above. For other product information or if you have questions regarding regulations or standards not covered in this document please contact 3M Separation and Purification Sciences Division.

1) Business Address

3M Company
3M Separation and Purification Sciences Division
3M Center
St. Paul, MN 55144, USA

2) Intended and Restricted Uses

Intended Use and Product Selection:

The 3M™ LifeASSURE™ BFS filter products are intended for use in industrial and Food and Beverage (F&B) filtration applications of gases in accordance with the applicable product instructions and specifications. Refer to the specific 3M LifeASSURE BFS product's data sheet to determine whether it includes a F&B designation and can be used for such applications.

Since there are many factors that can affect a product's use, the customer and user remain responsible for determining whether the 3M product is suitable and appropriate for the user's specific application, including users conducting an appropriate risk assessment and evaluating the 3M product in user's application.

Restrictions on Use:

3M advises against the use of these 3M products in any application other than the stated intended use(s), since other applications have not been evaluated by 3M and may result in an unsafe or unintended condition. Do not use in any manner whereby the 3M product, or any extractable or leachable from the 3M product, may become part of or remains in a medical device, drug, cosmetic supplement, infant formula; or in applications involving life-sustaining medical applications or prolonged contact with internal bodily fluids or tissues.

3) Product Descriptions Covered by this Document

Type	Configuration	Nominal Length Code (Inches)	End Modification Code	Gasket/O-ring Material Code
BFS020	**A**	**01 –** 10 in. **02 –** 20 in. **03 –** 30 in.	**B –** 226 O-ring & spear **F –** 222 O-ring & flat cap	**A –** Silicone

4) Composition

Membrane	PTFE
Support Layer	Polypropylene
Core, Cage, End caps/Modifications	Polypropylene
Support Ring	Polypropylene + Stainless Steel
O-rings	Silicone

5) Compliance with Regulatory and Industry Standards

SDS (US OSHA)
This product is an article and therefore is not subject to the requirements of the US Occupational Safety and Health Administration's (OSHA) Hazardous Communications Standard 29 CFR 1910.1200(b)(6)(v) to provide a Safety Data Sheet (SDS).

SDS (EU)
This product is defined as an article under REACH and does not require a Safety Data Sheet under Article 31 of Regulation (EC) No. 1907/2006.

Food Contact FDA 21 CFR (US)
The wetted component materials, when used in accordance with 3M™ LifeASSURE™ BFS Series Filter Cartridge intended uses and instructions, have been evaluated and found to comply to United States Food and Drug Administration (Code of Federal Regulations) 21 CFR 174-186 Regulations for Indirect Food Contact Compliance.

PTFE	177.1550 (for repeated use)
Polypropylene	177.1520
Silicone	177.2600

The PTFE materials of construction sited comply with FDA 21 CFR Table 2 of §176.170(c) under conditions of use B-H with all food types for repeated use.

The polypropylene materials of construction sited comply with FDA 21 CFR Table 2 of §176.170(c) under conditions of use B-H with all food types.

The stainless-steel components belong in the SAE 300 series alloy group and are thus considered acceptable for food contact applications per NSF/ANSI Standards 51 4.2.1.

Food Contact – Regulation (EC) 1935/2004 (EU)
3M LifeASSURE™ BFS Series Filter Cartridges comply with the requirements of Regulation (EC) 1935/2004 in that; plastic materials comply with Regulation (EU) 10/2011, all monomers and additives are listed in Annex I and migration testing in simulants B (3% acetic acid), D1

(50% ethanol) has shown that total and specific migration limits will not be exceeded under normal conditions of use. The product is compliant with the requirements of regulation (EC) 1935/2004 for food contact for use in aqueous, acidic, alcoholic, and dairy foods. Non-plastic materials comply with other recognized standards. A full declaration of compliance is available, contact 3M Separation and Purification for details.

Regulation (EC) 1907/2006 REACH

3M™ LifeASSURE™ BFS Series Filter Cartridges are articles with no intended release of a chemical substance, under the REACH regulation (Article 3(3)) and are therefore not subject to preregistration or registration requirements.

Regarding Substances of Very High Concern (SVHC) to the best of 3M's knowledge, the chemicals from the Candidate List as amended on 8th July 2021 are not present at or above 0.1%.

The filter cartridges as supplied by 3M do not meet the criteria for classification as hazardous according to the CLP regulation No 1272/2008. Therefore, they are not within the scope of Regulation (EC) 1907/2006 Article 31 requiring the provision of a safety data sheet.

Directive 2011/65/EC RoHS

3M™ LifeASSURE™ BFS Series Filter Cartridges are not electrical and do not rely on electrical currents or electromagnetic fields to operate, they are therefore not in the scope of this directive. To the best of 3M's knowledge, the product does not contain any of the Listed Substances in excess of the maximum concentration values in the Directive.

V2021b1

Limitation of Remedies and Liability: In the event any Product is proven not to conform with 3M's certification, then to the extent permitted by law, 3M's entire liability and Buyer's exclusive remedy, will be at 3M's option either: (i) replacement of Product with a conforming product, or (ii) refund of the purchase price paid by Buyer for each non-conforming Product, within a reasonable time after written notification of said non-conformance and return of said Product to 3M. 3M shall not under any circumstances be liable for direct, incidental, special, or consequential damages (including but not limited to loss of profits, revenue, or business) related to or arising out of this certification, including, the use, misuse or inability to use the Product. Unless stated otherwise in writing, the foregoing language cannot be waived, modified, or supplemented in any manner whatsoever.

Certified by:

Emily Praznik
Regulatory Affairs

3M Science. Applied to Life.
Separation and Purification Sciences Division (SPSD)
3M Center, 236-2A-07 | St. Paul, MN 55144-1000 | United States
Office: +1 651 736 8281
eepraznik@mmm.com

Date Issued: November 22nd, 2021

VII. Appendix B
Article Information Sheet

Article Information Sheet

This Article Information Sheet is provided as a courtesy in response to a customer request. A Safety Data Sheet (SDS) has not been prepared for these product(s) because they are articles. Articles are not subject to the Occupational Safety and Health Administration's Hazard Communication Standard (29 CFR 1910.1200(b)(6)(v)). As defined in this standard: "Article" means a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical, and does not pose a physical hazard or health risk to employees.

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SECTION 1: Identification

1.1. Product identifier
3M™ LifeASSURE™ BFS Series Filter Cartridges

Product Identification Numbers
BFS020A01BA, BFS020A01FA, BFS020A02BA, BFS020A02FA, BFS020A03BA, BFS020A03FA

1.2. Recommended use and restrictions on use

Recommended use
Filter Cartridge

1.3. Supplier's details

MANUFACTURER:	3M Purification Inc.
DIVISION:	Separation and Purification Sciences Div
ADDRESS:	400 Research Parkway, Meriden, CT 06450-1018, USA
Telephone:	1-888-3M HELPS (1-888-364-3577)

1.4. Emergency telephone number
1-800-364-3577 or (651) 737-6501 (24 hours)

SECTION 2: Hazard identification

This product is exempt from hazard classification according to OSHA Hazard Communication Standard, 29 CFR 1910.1200.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt

Polypropylene Parts: Cage, Core, End Cap, Adapter Spear, Connector, Non-woven Membrane Support, and Netting	9003-07-0	50 - 70
PTFE Membrane	9002-84-0	25 - 40
Optional: Stainless Steel or Polysuflone Insert Ring	Mixture	0 - 10
O-Rings	Mixture	< 5

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation:
No need for first aid is anticipated.

Skin Contact:
No need for first aid is anticipated.

Eye Contact:
No need for first aid is anticipated.

If Swallowed:
No need for first aid is anticipated.

SECTION 5: Fire-fighting measures

In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Not applicable.

6.2. Environmental precautions
Not applicable.

6.3. Methods and material for containment and cleaning up
Not applicable.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
This product is considered to be an article which does not release or otherwise result in exposure to a hazardous chemical under normal use conditions.

7.2. Conditions for safe storage including any incompatibilities
No special storage requirements.

SECTION 8: Exposure controls/personal protection

This product is considered to be an article which does not release or otherwise result in exposure to a hazardous chemical under normal use conditions. No engineering controls or personal protective equipment (PPE) are necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Solid
Color	White
Odor	Odorless
Odor threshold	*No Data Available*
pH	*Not Applicable*
Melting point	*No Data Available*
Boiling Point	*Not Applicable*
Flash Point	*Not Applicable*
Evaporation rate	*Not Applicable*
Flammability (solid, gas)	Not Available
Flammable Limits(LEL)	*Not Applicable*
Flammable Limits(UEL)	*Not Applicable*
Vapor Pressure	*Not Applicable*
Vapor Density	*Not Applicable*
Density	*No Data Available*
Specific Gravity	*No Data Available*
Solubility In Water	*Not Applicable*
Solubility- non-water	*Not Applicable*
Partition coefficient: n-octanol/ water	*Not Applicable*
Autoignition temperature	*Not Applicable*
Decomposition temperature	*No Data Available*
Viscosity	*Not Applicable*

SECTION 10: Stability and reactivity

This material is considered to be non reactive under normal use conditions.

SECTION 11: Toxicological information

Inhalation:
No health effects are expected

Skin Contact:
No health effects are expected

Eye Contact:
No health effects are expected

Ingestion:
No health effects are expected

Additional Information:

This product, when used under reasonable conditions and in accordance with the directions for use, should not present a health hazard. However, use or processing of the product in a manner not in accordance with the product's directions for use may affect the performance of the product and may present potential health and safety hazards.

SECTION 12: Ecological information

This article is expected to present a low environmental risk either because use and disposal are unlikely to result in a significant release of components to the environment or because those components that may be released are expected to have insignificant environmental impact.

SECTION 13: Disposal considerations

Dispose of contents/container in accordance with the local/regional/national/international regulations.

SECTION 14: Transport Information

Please contact the emergency numbers listed on the first page of the SDS for Transportation Information for this material.

SECTION 15: Regulatory information

Chemical Inventories
This product is an article as defined by TSCA regulations, and is exempt from TSCA Inventory requirements.

SECTION 16: Other information

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