Cryptosporidium Protection with LifeASSURE™ BLA Series Filters

Introduction

Cryptosporidium is a protozoan parasite that causes disease (*cryptosporidiosis*) in humans. Because it can form a protective cyst, it is very resistant to standard water treatment methods and can remain in drinking water after conventional processing.

Figure 1 - *Cryptosporidium parvum*

Outbreaks of *cryptosporidiosis* and other diseases related to pathogenic protozoa, have increased the scrutiny of bottled water quality and the quality of other beverages. The United States Centers for Disease Control and Prevention (CDC) and the United States Environmental Protection Agency (EPA) have issued guidelines recommending processes to control *Cryptosporidium*, including the use of filters that carry a 1.0 µm absolute retention rating.

However, a filter stamped 1.0 µm is not necessarily adequate to stop *Cryptosporidium* in bottled water processes, since there is no industry standard by which all filters are rated. Retention ratings are highly dependent on parameters such as particle size, distribution, flux, and differential pressure across the filter. Therefore, a 1.0 µm rated filter from one supplier may not provide the same protection as a 1.0 µm rated filter from another.

Since no industry standard exists regarding a retention rating method among filter manufacturers, the CDC/EPA recognize Standard 53 from NSF International as a qualifying standard. NSF International is a respected, independent third party certification laboratory specializing in issues related to the water industry. Standard 53, Cyst Reduction, is a rigorous test that certifies a filter's ability to retain *Cryptosporidium*.

This Customer Application Brief describes the benefits of the LifeASSURE™ BLA Series membrane filter cartridge in protecting beverage grade water from *Cryptosporidium* contamination. Those benefits include:

- Certification of cyst reduction performance to NSF ANSI/NSF Standard 53, to ensure reliable, consistent reduction of pathogenic protozoan cysts, such as *Cryptosporidium* and *Giardia*.
- The membrane and cartridge design, which results in faster flow rates and longer service life to reduce operating costs.
- Reduction of HPC (heterotrophic plate count) bacteria, eliminating a cause of off taste and odor.
- No generation of disinfection by-products, such as bromate.

Cryptosporidium

Cryptosporidium parvum, and a similar larger organism, *Giardia lamblia*, are enteric protozoa that can infect the gastrointestinal tract of humans and animals. Outbreaks of cryptosporidiosis have led to severe illness in many parts of the world (www.cdc.gov/crypto/). People infected with *Cryptosporidium* contract an illness that ranges from mild gastroenteritis to vomiting, diarrhea, in the case of immuno-compromised individuals. *Cryptosporidium* oocysts are typically between 4-6 µm in size (Figure 1), and are very resistant to disinfection by standard methods employed by the beverage industry. *Cryptosporidium* is difficult to detect and survives for extended periods in the natural environment as a cyst. It can infect surface water used as a municipal drinking water supply, and ground water under the influence of surface water – both of which are common sources of beverage grade water. While the U.S. EPA is taking steps to decrease the likelihood of *Cryptosporidium* contamination in public water sources, sources not under their jurisdiction are still at risk.

Typical Process

Beverage and bottled water systems can vary widely. The schematic (Figure 2) is intended to serve as a guide only. Generally, bottled water production requires three main components of filtration – particulate reduction, equipment protection, and microbiological control. Particulate reduction filters eliminate turbidity causing particles from the product water. Particles from the source water as well as particles generated from transfer piping, storage tanks, carbon and sand filters all can raise turbidity to an unacceptable level. Equipment protection filters are typically employed upstream of reverse osmosis (R.O.) membranes or distillation equipment to help protect them from premature fouling and additional maintenance expenditures.

Microbiological control filters are typically installed at the end of the filtration scheme, just prior to the filling machine. Additional control steps such as ozonation and UV light may be employed as part of what the International Bottled Water Association (IBWA) terms a "multi-barrier approach". In this approach the use of redundant security steps help assure microbiologically safe product water.

The use of a prefilter prior to the final filter step is sometimes required to improve process economics. A less costly, depth style prefilter provides high capacity protection against particles that would plug the final, *Cryptosporidium*-retentive filter.

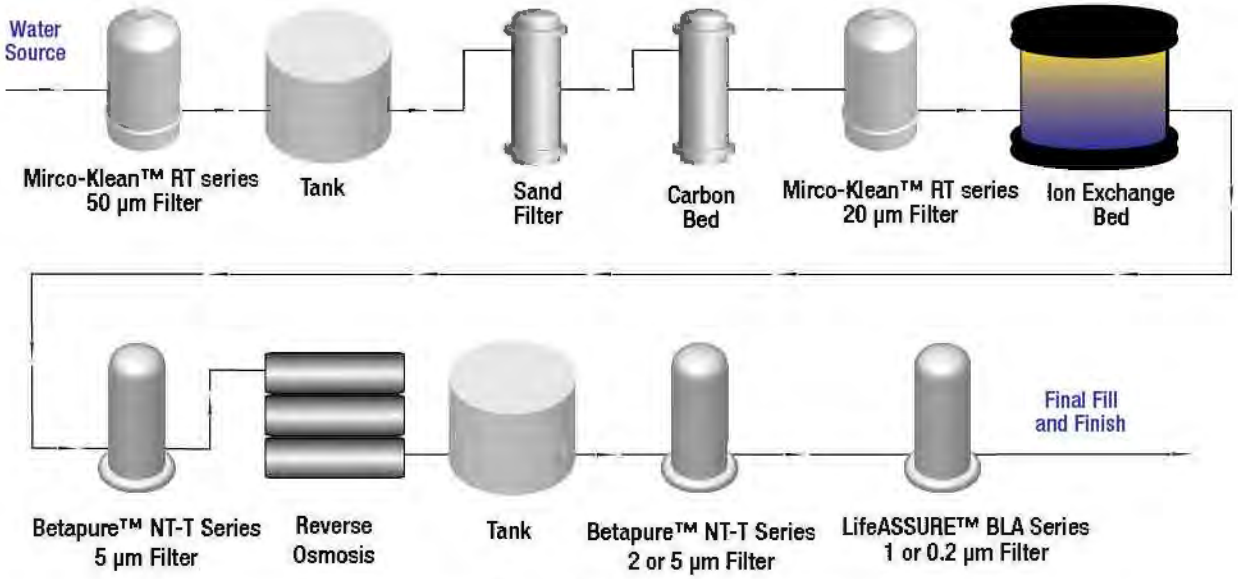

Figure 2 — Typical Bottled Water Process

The Solution

The LifeASSURE™ BLA series BLA100 filter is an effective barrier against protozoan cysts *Cryptosporidium* and *Giardia* in water production for the beverage industry.

The LifeASSURE BLA series filter incorporates's advanced multi-zone microporous Nylon 6,6 membrane technology. As the SEM photo of the LifeASSURE BLA series membrane cross section below demonstrates (Figure 3), the membrane is constructed with a single layer of membrane consisting of an "open" zone on the upstream side of the membrane and a "tighter" zone on the downstream side. In effect, the upstream zone acts as a prefilter, capturing larger particles and bacteria, while the tighter downstream zone provides retention of smaller particles and bacteria. This multi-zone structure results in greater contaminant capacity, while maintaining fast flow rates. The combination provides the end-user with the security and reliability of consistently high cyst and bacteria reduction along with the enhanced economics of longer lasting, faster flowing filter assemblies as compared to competitive alternatives..

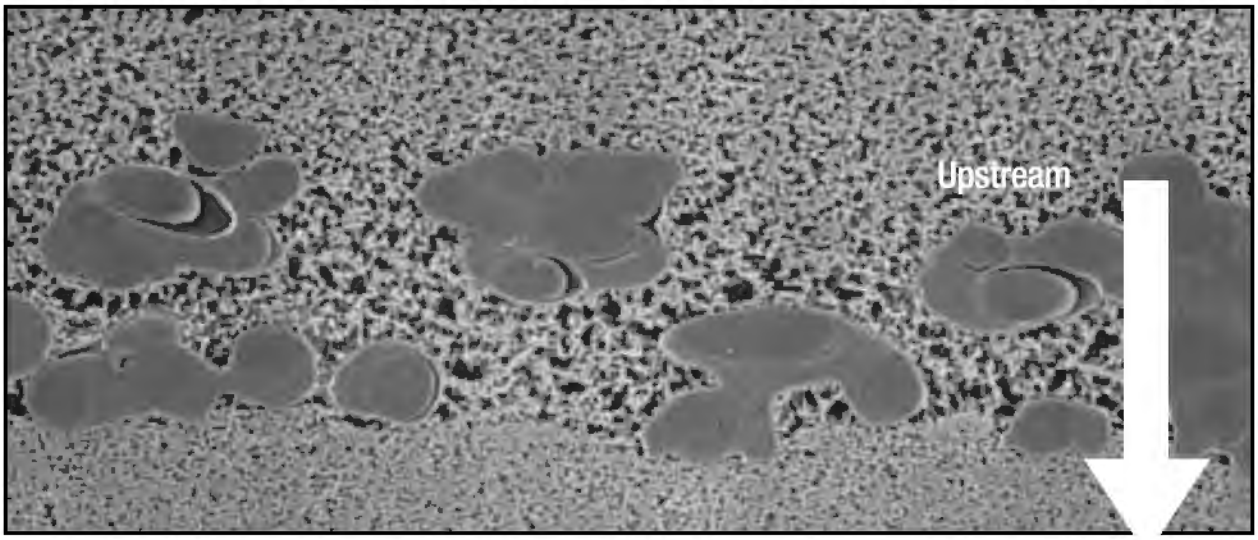

Figure 3 — Cross section of LifeASSURE™ BLA Series multi-zone microporous Nylon 6,6 membrane

Four particular areas were investigated in relation to the suitability of LifeASSURE BLA series filters for *Cryptosporidium* protection in the bottled water industry: 1. independent, third-party certification of *Cryptosporidium* reduction, 2. filter cartridge service life, 3. filter cartridge flow rates and , 4. HPC (heterotrophic plate count) bacteria retention.

Benefits of the LifeASSURE™ BLA Series Filter NSF Certified *Cryptosporidium* Reduction

NFS International is an authority for evaluating and certifying *Cryptosporidium* reducing filters. Filters carrying the NSF International mark (Figure 4) have been tested and certified by NSF International to Standard 53 for cyst reduction. LifeASSURE BLA series filters have been tested and certified to this standard at 3 gpm and carry this mark.

Unlike many other filters that are certified by the filter manufacturer themselves, LifeASSURE BLA series filters carry the NSF logo and are supplied with a certificate of quality, assuring conformance to high quality standards.

Cartridge Service Life

A laboratory study was conducted to measure the relative service life of filters marketed as cyst reducing. The following filters were tested: LifeASSURE BLA series BLA100, Pall AbsoLife, Osmonics Flotrex and Graver Technologies LLC. VTEC®.

Figure 4 — NSF International

A test rig was used so that all filters were tested simultaneously, each at a constant flow rate of 3 GPM. A model contaminant (kaolin clay and anhydrous sodium pyrophosphate) was added to the upstream water at a concentration of 10 ppm to induce plugging. All filters were run until a terminal differential pressure of 20 psid over their initial clean pressure drop was achieved. The data in Chart 1 are normalized with the longest lasting filter, LifeASSURE™ BLA Series filter, set at 100%.

As the data show, the LifeASSURE BLA series filters lasted 56% longer than the nearest competitor, and nearly four times longer than the competitor with the least throughput.

Cartridge Flow Rate Performance

Chart 1—Cartridge Service Life

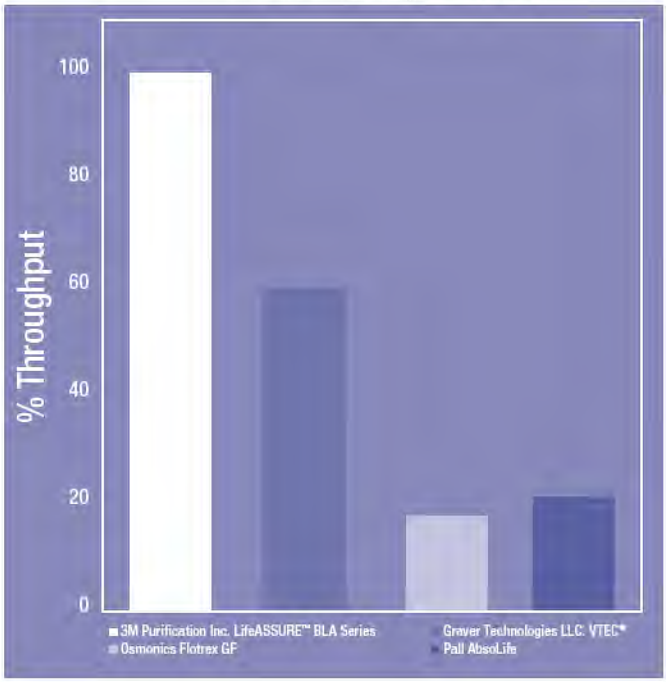

Chart 2—Flow Rate Comparison

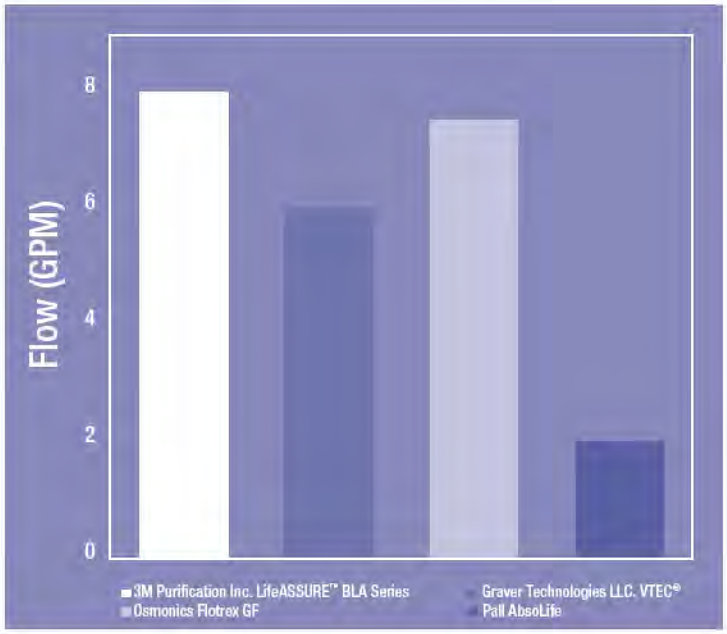

Table 1 —Example Using a System Flow Rate of 80 GPM

	Filter Selection	Flow Rate @ 1 psid (GPM)	10" Filters Required
Option #1	LifeASSURE™ BLA Series BLA100	8	10
Option #2	Pall AbsoLife 1.0 µm	2	40

LifeASSURE BLA series cartridge filters are designed with Advanced Pleat Technology design providing up to 50% more filter media surface area than competitive filters while maintaining proper flow paths between media pleats. The result of this technology, combined with the multi-zone microporous membrane design, is a filter cartridge with the ability to flow faster (Chart 2). This leads to longer on-stream service life in existing filter housings, or, in a new installation, the ability to use smaller filter housings with fewer cartridges to achieve a given flow rate. The example in Table 1 illustrates this benefit.

As data in Table 1 shows, a bottler designing a system with a demand of 80 GPM would require four times as many Pall AbsoLife filters compared to LifeASSURE BLA series filters to provide this flow at a 1 psid initial clean differential pressure. In addition to the extra outlay for cartridges, the bottler would also be required to purchase a much larger filter housing, and would incur longer filter change-out times (four times the number of cartridges to change) and greater labor costs.

HPC Bacteria Reduction

Heterotrophic plate count (HPC) organisms are an increasing concern to the bottled water and beverage industries. The EPA has an informal standard of 500 CFU/ml as an indicator of the presence of coliforms. Considered as a group, heterotrophs are not pathogenic, although elevated levels can indicate improper sanitation procedures in a bottling plant. High levels of microbial growth can affect the taste and odor of drinking water and may indicate the presence of nutrients and biofilms.
Certain equipment, such as activated carbon beds, can actually increase the level of HPC bacteria in the water if not cleaned and sanitized on a regular basis. Activated carbon, with an estimated 45,000 square meters of surface area per pound of media, offers a good

environment for bacteria to grow. Installed as the final filter in a bottling line, membrane filters that reduce high concentrations of HPC bacteria, without sacrificing filter service life or flow, are desirable.

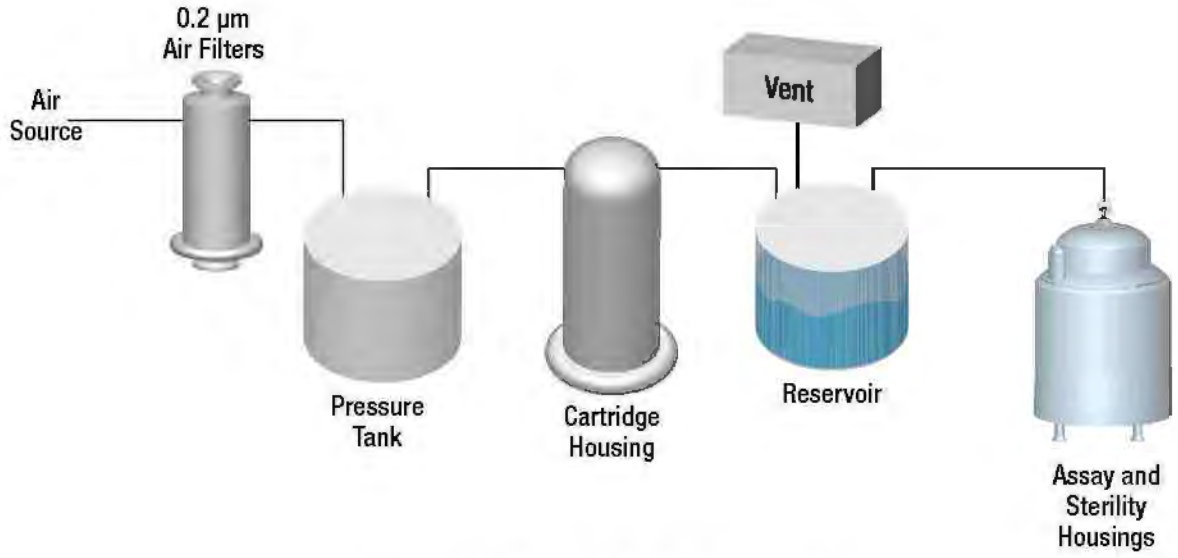

Figure 5 — Bacteria Retention Test Assembly

To evaluate the efficiency of various membrane filters, bacterial retention studies are often performed. Bacteria retention studies are not only extremely sensitive indicators of efficiency, they also address an important need in the beverage industry, namely, bioburden control. Bacteria retention studies were conducted using the test system shown in Figure 5. Bacteria retention testing of membrane filters has been well described. Essentially, a monodispersed solution of a known bacteria is used to challenge the test filter. This solution in passed through the test filter and then the filtrate is then passed through an analysis membrane filter disc. This disc is subsequently incubated for enumeration of bacterial colonies. A comparison of the number of influent bacteria to the number of bacteria in the filtrate is made. The comparison is often expressed logarithmically according to the formula: Log Reduction Value (LRV) = $\log_{10}$ (number of bacteria entering the filter/number of bacteria exiting the filter). The higher the LRV value, the greater the bacteria reduction. Additionally, since LRVs are expressed logarithmically, each unit of increase is equal to an order of magnitude (x10) increase in performance. As an example, a filter that provides an LRV of 7 is ten times more retentive than a filter that provides an LRV of 6, 100 times more retentive than a filter that provides an LRV of 5, and so on.

In tests conducted with *P. fluorescens*, LifeASSURE™ BLA series BLA100 grade filters and competitive filters exhibited average log reduction values depicted in Table 2.

The cartridges were challenged in accordance with the following testing parameters.

- Challenge organism: *P. fluorescens* (ATCC) # 49642.
- Minimum challenge concentration: 7.3×10^{7} CFU/cm^2 of filter media
- Average flow rate: 2.7 GPM per 10" cartridge
- All plates were incubated at 26 °C for seven days prior to evaluating final results.

Table 2 —Bacteria Retention Test Results

Filter	Part Number	Average Influent Bacteria Challenge Conc. (CFU)	Average LRV
LifeASSURE™ BLA Series	BLA100B01FD	6.13×10^9	6.5
Osmonics Flowtrex GF	FGF011EGS	3.3×10^8	0.8
Graver Technologies LLC VTEC®	674151	2.7×10^9	1.5
Pall AbsoLife	WCP01NB21tS	4.4×10^8	0.1

As the data in Table 2 show, LifeASSURE™ BLA series filters reduced *P. fluorescens* at a much higher rate than any filter tested. Furthermore, the test conditions, particularly the challenge level of 7.3×10^7 CFU/cm² of filter media, are "worst case" conditions and are not expected to occur in a bottling plant. This leaves a wide "safety zone" between the retentive capability of the LifeASSURE BLA series filter and actual bacteria levels in the product water of a given facility.

Disinfection By-products

The U.S. EPA and the U.S. Food & Drug Administration (FDA) have issued a regulation* limiting bromate, a disinfection by-product, in drinking water. Bromate is generated when the naturally occurring bromide ion is exposed to ozone, such as in the case of a bottled water plant employing ozone for microbiological control.

The International Bottled Water Association (IBWA) has also established a control limit of 10 ug/L (10 ppb) of bromate for member bottlers. The IBWA has also recommended membrane filtration as an option in providing microbiological control, without the use of ozone, as part of a "multi-barrier" approach to water safety. Membrane filters, such the LifeASSURE BLA series filter, provide users with effective microbiological control without the need for ozone, thereby eliminating the generation of disinfection by-products.

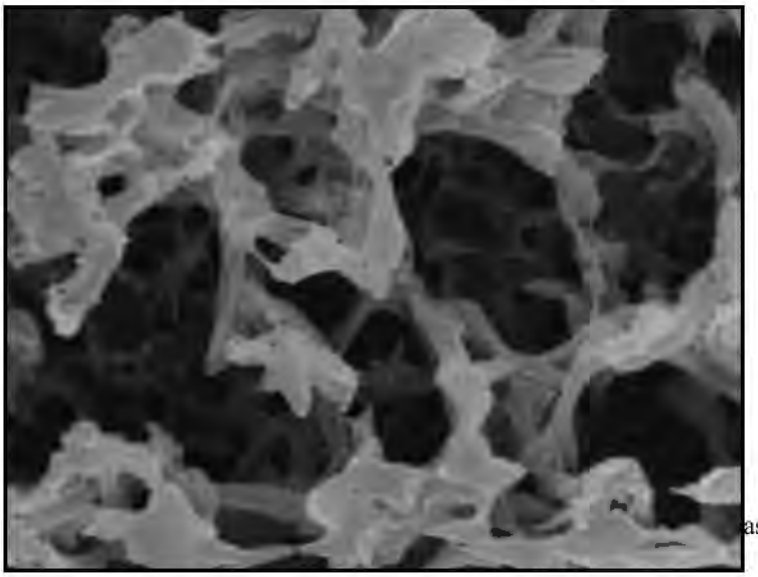

Figure 6 -Bacteria trapped on LifeASSURE™ BLA Series membrane surface

*[(b)(4)(iii)(H) in Section 165.110 of 21 CFR]

Conclusion and Summary

Pathogenic cysts such as *Cryptosporidium* and *Giardia* can be present in surface water as well as ground water under the influence of surface water. These water sources are often used for bottled water and other beverage grade water. Outbreaks of cryptosporidiosis and other diseases related to pathogenic protozoa, have increased the scrutiny of bottled water quality and the quality of other beverages. Membrane filtration has been shown to be an effective barrier against cyst contamination.

To assure consistency of performance, membrane filter performance should be validated by a well respected independent party standard, such as NSF International Standard 53. Additional considerations for the beverage processor, such as filter cartridge flow rate and service life, impact the cost of implementing this filtration. Filters designed to flow faster and last longer offer an economic benefit in that the beverage processor can employ smaller filter housings and change the filters less frequently. Lastly, filters that reduce high levels of HPC bacteria provide additional protection against organisms that can potentially effect beverage taste, odor and consistency.

This Customer Application Brief describes the benefits of LifeASSURE™ BLA series membrane filter cartridges in protecting beverage grade water from *Cryptosporidium* contamination. Those benefits include:

- Certification of performance to NSF International Standard 53, cyst reduction, to ensure reliable, consistent reduction of pathogenic protozoan cysts.
- The membrane and cartridge design, result in faster flow rates and longer service life to reduce operating costs.
- Reduction of HPC (heterotrophic plate count) bacteria, preventing a cause of off taste and odor.
- No disinfection by-products, such as bromate, are generated.

References

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Denn, J, "Heterotrophic Bacteria Debate Continues", Water Technology, October, 1999

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Reynolds, K., "Heterotrophic Plate Count Bacteria and Drinking Water", Water Conditioning & Purification, January 1999.

MacCormick A, "*Cryptosporidium* – Driving the Shift Towards Microfiltration?", Filtration & Separation, January/February 1999.

Literature References

Literature Description	Literature Identification
LifeASSURE™ BLA Series Filter Cartridges	LITLABW1 70020187657
Micro-Klean™ Series Filter Cartridges	LITCBK002 70-0201-8689-9
Betapure™ NT-T Series Filter Cartridges	LITCPN1 70020187202

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