Antimicrobial Laundry Additive

Frequently Asked Questions

Q. What role do textiles play in the spread of infection?

A. Healthcare textiles such as bed linens, gowns, and curtains can become contaminated with pathogens in four ways:

1) Microbial shedding from patients and personnel within the healthcare facility

2) Contact of textiles with humans and other contaminated surfaces during storage and handling

3) Contact of textiles with humans and other surfaces within the laundry facility and during transportation

4) Improper reprocessing of textiles

The patient represents a primary epicenter of microbial spread with the textiles being the barrier between the patient and the rest of the hospital environment. Similarly, healthcare workers can also carry and shed pathogenic microbes onto clothing and other surfaces. It has been reported that up to 60% of hospital staff uniforms are colonized and 55% of samples from clean bed linens were contaminated even before contact with patients. Once textiles become contaminated, microorganisms like Staphylococci and Enterococci can survive for extended periods of time on materials like soft surfaces, allowing them to transmit bacteria onto patients and/or other surfaces (source: https://www.journalofhospitalinfection.com/article/S0195-6701(15)00142-5/abstract). Hospital linens that have been contaminated with mold have been reported to be the cause of several outbreaks resulting in death (source: http://www.cnn.com/2017/01/28/health/moldy-hospital-bed-linen-deaths/).

Q. What scientific data exists about textile contamination?

A. There are numerous studies demonstrating that textiles in the hospital environment become easily contaminated with bacteria, mold, and mildew from the hospital environment. Recent studies have shown that commercial laundry processes using industrial detergents and high disinfecting temperatures do not completely eliminate the presence of bacteria such as Clostridium difficile. Another study showed that hospital privacy curtains area a breeding ground for MRSA, and by day 14, 87% test positive for it. Review our educational packet here: http://www.appliedsilver.com/resources/
Q. What is SilvaClean and how does it work?

A. SilvaClean is a patented, smart technology platform that is installed at a laundry facility. It infuses textiles with silver ions during the laundry rinse cycle, where they bond with fabrics to residually kill pathogens, mold, and mildew, eliminating odors, and helping to remove stains and reduce static. The SilvaClean system is a dispensing device enabled by the Internet of Things (IoT) that doses the EPA-approved SilvaClean chemistry onto textiles during the laundry rinse cycle, leaving fabrics with residual antimicrobial properties even after laundering (e.g., in storage, during handling, and in use). When linens are being used, SilvaClean remaining in linens will reduce levels of *S. aureus* and *C. albicans* by 99.9% after 6 hours of contact; *K. pneumoniae*, Vancomycin resistant *Enterococcus faecalis*, Extended-spectrum beta-lactamase positive *E. coli*, and *A. baumannii* by 99.9% after 3 hours of contact; and Methicillin-Resistant *S. aureus* by 99.9% after 9 hours of contact. As part of a diligent infection control program, experts recommend that a healthcare facilities should seek to reduce or eliminate exposure to pathogens to the greatest extent possible. One practical inexpensive way to aid in this effort is to use SilvaClean.

Q. What is the impact of SilvaClean treatment on textiles?

A. It is widely accepted that textiles are fomites capable of harboring microorganisms for extended periods of time. This occurrence results in two potential outcomes that SilvaClean has a direct impact on:

1) **Spread of microorganisms from this source to other surfaces.** In the hospital setting, these microorganisms, when pathogenic or infectious in nature, can potentially cause Healthcare Associated Infections (HAIs). When SilvaClean is introduced as a component of an Infection Control bundle, it can aid in controlling environmental sources of microbial contamination. A study done by Openshaw et. al. and published in the American Journal of Infection Control demonstrates that treated hospital linens had a lower microbial load (including lower loads of *Staphylococcus aureus* and MRSA) before during and after patient use. Additionally, Applied Silver has also published a clinical surveillance study done at three hospitals where an Infection Control bundle, of which SilvaClean was a part of, resulted in a 43% reduction in HAI rates over the period of the study.

2) **Deterioration of fabric over time due to metabolic activities of the microorganisms.** SilvaClean reduces the amount of stain- and odor-causing bacteria, mold, and mildew on the fabrics, protecting them and extending the life of use.

Q. How is SilvaClean product registered and/or approved for use by the government?

A. SilvaClean is an antimicrobial laundry additive with residual activity that reduces post-laundry contamination. SilvaClean product registration falls under the regulatory authority of the Environmental Protection Agency (EPA), specifically, the Antimicrobials Division (7510P) under the Office of Pesticide Programs (OPP). EPA
regulates pesticides under the statutory authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which defines an antimicrobial pesticide as that which is intended to disinfect, sanitize, reduce, or mitigate growth of development of microorganisms; or protect inanimate objects from contamination caused by microorganisms.

Read more at the EPA website here: https://www.epa.gov/pesticides/antimicrobial-pesticides

Q. **Why are hospitals adopting SilvaClean?**

A. There is more and more evidence that the hospital environment contributes to the development and spread of Healthcare Associated Infections (HAIs). As part of a diligent infection control program, experts recommend that a hospital seek to reduce or eliminate exposure to pathogens to the greatest extent possible. One practical, inexpensive way to aid in this effort is to use SilvaClean laundry additive as a passive horizontal intervention that can augment all other Infection Control bundles. SilvaClean can be applied to all existing linen inventory with minimum change in Standard Operating Procedures and no additional training, creating an easy-to-implement, cost-effective Infection Control strategy. SilvaClean is currently being implemented for patient linens as well as cubicle curtain programs at various hospitals.

Q. **Is SilvaClean registered with the EPA for public health uses?**

A. Yes. Under the product registration “Laundry additive for residual activity against post-laundry contamination”, the EPA has approved SilvaClean for public health uses. SilvaClean can be recommended as a useful addition to aid Infection Control at hospitals and sports programs.

See approved EPA label on the EPA’s Website:

Q. **Is SilvaClean registered with the EPA for non-public health uses?**

A. Yes. Under the product registration “treated article exemption”, the EPA has also approved SilvaClean for use in protection of treated textiles from stain- and odor- causing bacteria and fungi (mold and mildew).

See approved EPA label on the EPA’s Website:

Q. **How can I justify the price of SilvaClean to my organization?**

A. Infection control programs that include SilvaClean along with standard practices such as hand hygiene and
hard surface cleaning have been demonstrated to have reduced HAI rates in clinical settings producing a positive return on investment. The cost of treating your textiles with SilvaClean is about 50% less than using disposables. SilvaClean antimicrobial textile treatment is implemented in the laundering process on current linen inventory. No new textiles need to be purchased. SilvaClean does not require any new protocols or procedural changes unlike other technologies (e.g., copper hard surfaces, ultraviolet light machines, etc.). When compared to other infection prevention technologies as relative cost per patient day, SilvaClean is a cost-effective option. For example, SilvaClean is more affordable than threaded/embedded antimicrobial textiles, copper hard surfaces, disposable textiles, UV light robots, hydrogen peroxide vapor machines and even bleach!

Q. Is SilvaClean safe to use in pediatric wards?
A. Yes, SilvaClean is approved by the EPA to be used for industrial use including use in all hospitals which include neonatal, pediatric, PICUs, etc.

Q. Has SilvaClean been tested to ensure it can be used with infants?
A. Yes. SilvaClean is safe to use with infants. The exposure levels have been analyzed and approved by EPA to be safe for use with infants.

Q. Is there a risk of allergic reactions to SilvaClean?
A. SilvaClean utilizes pure silver and there are no known allergic reactions to silver in this form. Perceived silver allergies such as those to sterling silver jewelry are actually reactions to other elements in the silver-based alloy, most commonly nickel.

Q. Is SilvaClean safe to use in MRI/CAT scanners?
A. Yes. SilvaClean is safe for MRI/CAT scanners because the ionic silver in SilvaClean treated fabrics is far below the threshold to interfere with these machines. This is achieved through a proprietary micro-dosing process that allows for even dispersion of ionic silver, providing consistent antimicrobial efficacy without creating interference for routine medical procedures.

SilvaClean has been used in several hospitals for a number of years with no reported issues in MRI/CAT scanners. Silver has been in routine use in other medical applications with no concerns for MRI/CAT scanners. Below are some examples.
1) A study compared silver dressings with non-silver dressings in a series of MRI sequences, which showed no deflection, torsion, safety, or image distortion concerns for the silver dressings.
   a) Concentrations of silver on wound dressings in this study are above silver concentrations in SilvaClean treated fabrics.
   b) Reference: MRI Compatibility of Silver-based Wound Dressing

2) A study determined that a wound dressing containing ionic silver was safe for MRI machines according to ASTM Standard F2503-05 and showed similar magnetic and electric properties as human tissue.
   a) Concentrations of ionic silver in this study are 1,000 to 10,000x the amount of ionic silver in SilvaClean.
   b) Reference An evaluation of MRI safety and compatibility of a silver-impregnated antimicrobial wound dressing
      https://www.jacr.org/article/S1546-1440(09)00117-3/abstract

Q. What outcomes studies support the use of SilvaClean in an Infection Control program?

A. EPA approved the public health claims for SilvaClean based on third party Good Laboratory Practice (GLP) data demonstrating the following kill times:

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Hours of Contact</th>
<th>Textile</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>6 hours</td>
<td>Cotton, cotton/polyester blend,</td>
</tr>
<tr>
<td><em>Klebsiella pneumoniae</em></td>
<td>3 hours</td>
<td>or microfiber</td>
</tr>
<tr>
<td>Vancomycin-resistant <em>Enterococcus faecalis</em> (VRE)</td>
<td>3 hours</td>
<td>Cotton, cotton/polyester blend</td>
</tr>
<tr>
<td>Extended-spectrumbeta-lactamase (ESBL) positive <em>Escherichia coli</em></td>
<td>3 hours</td>
<td></td>
</tr>
<tr>
<td><em>Acinetobacter baumannii</em></td>
<td>3 hours</td>
<td></td>
</tr>
<tr>
<td><em>Candida albicans</em> (yeast)</td>
<td>6 hours</td>
<td></td>
</tr>
<tr>
<td>Methicillin-Resistant <em>Staphylococcus aureus</em> (MRSA)</td>
<td>9 hours</td>
<td></td>
</tr>
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These data were supported by multi-year clinical studies (conducted at three community hospitals) in collaboration with a Stanford University scientist confirming that textiles are routinely re-contaminated with microbes during storage, handling, and use, even after undergoing a certified hygienically clean laundry process. The study further demonstrated that by regularly laundering those textiles with SilvaClean, microbes, including *Staphylococcus*, were significantly reduced before, during, and after patient use.
In another independent study, microbial bioburden was evaluated pre- and post-SilvaClean treatment at four points in the laundry-hospital linen route including two in the laundry and two in the hospital. These studies also demonstrated a reduction in overall microbial bioburden in treated linens and curtains.

Notably, a significant reduction of 99% was observed even in linen samples that were relatively clean and were sampled straight out of the dryer. Additionally, infection control programs that include SilvaClean along with standard practices such as hand hygiene and hard surface cleaning have been demonstrated to have reduced microbial bioburden on hospital linens and HAI rates in clinical settings. In a peer-reviewed retrospective clinical surveillance study, a clinically significant reduction of 43% in overall HAI rates was observed in the time period that included SilvaClean as part of the routine hospital infection prevention bundle (with standard practices like hand hygiene and hard surface cleaning) versus the previous without SilvaClean.

Click here to review our clinical studies: http://www.appliedsilver.com/resources.

Q. Does SilvaClean change the way fabric looks or feels?
A. SilvaClean antimicrobial treatment does not change the way fabric looks, nor does it change the way it feels, and will improve the cleanliness of the fabric and reduce any odor attributed to microorganisms. In fact, it is impossible to tell that SilvaClean is present with the naked eye so Applied Silver has created a SilvaSure® test kit to detect for the presence of SilvaClean.

Q. What are the potential environmental impacts of SilvaClean treatment?
A. The SilvaClean product is registered for use as a laundry additive by the Federal EPA and the California Department of Pesticide Registration for industrial use. SilvaClean has been intensively tested for concentration of silver in effluents as part of that approval process. Any residual silver ions in the wastewater are at levels significantly below the EPA’s and the city Publicly Owned Treatment Works (POTW) requirements.

Q. What type of antimicrobial is SilvaClean?
A. SilvaClean employs silver ions that provide a complete killing mechanism against microbes. Silver ions in SilvaClean have a three-way kill mechanism:

1) Cell Lysis: Silver ions bind to the cell wall of the microbe, causing it to rupture

2) Cell suffocation: Once inside the cell, silver ions attach to the metabolic enzymes, suffocating the cells
3) Stops DNA replication: The silver ions bind to the strands of DNA to stop the replication process. In contrast, the action of traditional laundry detergents is generally limited to a single mode of action such as microbial cell lysis, that can be inefficient and cause some microbes to survive and multiply. A recent study has shown that commercial laundry processes using industrial detergents and high disinfecting temperatures do not completely eliminate the presence of bacteria such as Clostridium difficile (Tarrant et. al., Infect. Control & Hosp. Epidemiol., 2018, 0, 1-6).

Q. Is SilvaClean compatible with all laundry formulas?
A. Yes. SilvaClean is compatible with all brands of detergent, bleach, sours, softeners, breaks, etc. SilvaClean treatment does not change the way the fabric looks or feels. Silver ions are much smaller than the eye can see and cannot be seen on textiles and do not result in any discoloration of the treated textile. SilvaClean antimicrobial technology is designed for industrial water (i.e., softened water) but works efficiently with varying water profiles.

Q. Is SilvaClean made from Nano silver?
A. No, SilvaClean is a non-nanoscale silver ion-based laundry additive product. It is made up of silver ions, which should not be confused with nano-silver. Silver ions are what gives silver its antimicrobial properties. Ionic silver is easily measured and its delivery via the SilvaClean dosing system is tightly controlled by IoT. Nano-silver must shed silver ions to exhibit antimicrobial properties, and the rate of this release is hard to predict because it varies with the environmental variables (moisture, pressure, heat, etc.). The EPA has begun to revoke products with nano-silver, as they pose potential environmental risks.

Q. Can microorganisms develop a resistance to silver?
A. Multiple studies highlight the unique advantages that heavy metals provide to environmental microbial control, and one the presents an unconventional approach to addressing the growing public health crisis of antibiotic resistance. In particular, the use of silver for antimicrobial purposes is a practice that dates back thousands of years, and one that is still in use for various medical purposes. In theory, microorganisms can develop resistance to any antimicrobial agent when overused. However, there is very little evidence today that resistance to silver can become a major threat. In general, research indicates that resistance to heavy metals develops very slowly compared to traditional antibiotics (Goss et. al., Sci. Translat. Med. (2018), 10, 460). Due to silver ions’ multi-modal mechanism, it is more difficult for microbes to acquire resistance to silver compared to antibiotics that generally have a single mode of action. A recent study describes a systematic genetic screen to identify genes involved in silver susceptibility and resistance phenotypes. The results of this study identified that the activities of silver inside the microbes is much more extensive than previously thought and involves hundreds of individual genes (Gugula et.al., Genes (2018), 9, 344, 1-21). SilvaClean is applied at a dosage rate well above
the minimum inhibitory concentration to achieve a kill rate of greater than 99.9% over time. Additionally, silver is used in a wide variety of medical products such as ointments, hard surface coatings, etc. On page 54 of the CDC’s disinfection and sterilization guidelines, the center discusses the potential applications and safety of silver ions for environmental control:

Q. What’s the difference between SilvaClean and other Bactericides/Fungicides?
A. Unlike chlorine, quaternary ammonium compounds (quats) and peroxide additives, SilvaClean, when treated onto fabrics, is effective when the fabrics are used. When linens are being used, SilvaClean remaining in linens will reduce levels of S. aureus and C. albicans by 99.9% after 6 hours of contact; K. pneumoniae, Vancomycin-resistant Enterococcus faecalis, Extended-spectrum beta-lactamase positive E. coli, and A. baumannii by 99.9% after 3 hours of contact; and Methicillin-Resistant S. aureus by 99.9% after 9 hours of contact.

Q. How does SilvaClean compare to other antimicrobial textiles?
A. Antimicrobial textiles typically have silver or copper threads woven into the textile. This presents multiple disadvantages:

1) High cost of implementation: New inventory is required to be purchased, with average threaded linen cost being up to 2-3x higher than standard linen. Additionally, maintenance cost is also high. Copper/silver threaded linens are efficacious for only a limited number of uses after which a loss of efficacy is observed (e.g. 30 laundry cycles) and the linens have to be routinely replaced. Special inventory will also have to be purchased to replace lost linens. SilvaClean can be applied to all existing linen inventory, and re-applied each time the linen is laundered, making it a cost-effective solution that is easy to implement.

2) Reduced efficiency: For threaded antimicrobial textiles to work efficiently, microbes are required to come in contact with the silver ions as they are released from the threads. This process requires moisture and is uncontrolled, making the antimicrobial killing action less efficient. In contrast, SilvaClean is delivered as pure ionic silver onto textiles, and is active under wet or dry conditions and provides a highly efficient killing action against microbes.

3) Loss of efficacy over time: The re-laundering process of threaded textiles results in a loss of the metal threads over time, resulting in a reduction in efficacy. In contrast, SilvaClean is applied during each re-laundering step, efficacy levels are always consistently maintained.

4) Discoloration: Copper-threaded textiles in particular undergo visible discoloration with repeated washes. The rate of discoloration varies with individual pieces of linens.
Hospitals often have to manually color-match linens for individual rooms, adding to labor overhead.

**Q. How long does SilvaClean last?**

**A.** SilvaClean is laundry additive to reduce post-laundry contamination with residual antimicrobial activity. SilvaClean is stable in fabric and has shown efficacy in real-time stability studies over 4 years. When the fabric is re-laundered, it gets replenished with a fresh treatment of SilvaClean so you never have to worry about the textile remaining persistent. SilvaClean is not a substitute for any existing component of a diligent Infection Control program, and standard textile change-out protocols should be followed. If a gross contamination event occurs by a patient on a SilvaClean treated textile (e.g., bedding, gown) resulting in total saturation of the textile and/or a visible contiguous soiling (film) of bodily fluid such as blood or feces on the textile, we encourage the healthcare provider to follow their normal linen change-out protocols.