

An Organofunctional Silane Antimicrobial Technology: A Broad Spectrum, Non-Leaching Antimicrobial for Protection of Medical Goods and Facilities

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Introduction

The medical industry is challenged by the presence of microorganisms and the negative effects they cause. Deterioration, defacement and odors are all dramatic effects which occur from the microbial contamination of surfaces as varied as carpeting and medical non-woven fabrics. These surfaces can also act as a microbial "harbor," as most offer ideal environments for the proliferation of microorganisms that are harmful to buildings, textiles and humans. The ability to make surfaces resistant to microbial contamination has advantages in many applications and market segments. This is especially true in medical markets where many products have contributed a degree of aseptic sophistication beyond that required of consumer products.

Textiles (wovens, nonwovens, and composite fabrics), soft goods, equipment, and indoor hard surfaces used in a medical environment have unique microbial problems and their control is a complex chemical, physical, and microbiological task. The microbiological integrity of medical textiles and surfaces has been the object of numerous studies ranging from the sterilization of nonwovens to the evaluation of the barrier properties of engineered fabric. Test data generated generally support the fact that these materials contribute positively to the reduction of microorganisms in the medical environment. This contribution has been part of the medical community's awareness of the benefits of and the actions aimed at improving the hygienic nature of their environment as they take steps towards asepsis.

A wide array of uses has led such materials into end uses where microbiological problems are no longer simply questions of bio-deterioration. The problems caused by microorganisms in these uses have extended the needs of antimicrobial treatments

to controlling organisms that cause unsightly staining, odors, and reduction of organisms such that the fabrics are not considered harbors or transmission substrates for infectious organisms.

In order to understand microorganisms and their impact on medical materials, we must understand the uses and abuses of these materials. Just as the end-use is different for each article, the potential for microbial contamination and the ability to control this contamination are very different. Specific fabrics are designed for different end-uses. Specific antimicrobial agents are added for different end-use performances, needs and claims. Specific antimicrobial test methods with specific parameters are used to measure these activities. The variability of the antimicrobial agents, test methods, end-uses and performance claims are enormous and require a set of standards and guidelines that fulfill all possible applications. Testing and evaluating these performances under accelerated laboratory conditions with respect to the real-world effectiveness are often the most challenging of endeavors. This type of accelerated scientific testing is done for basic research, evaluating and optimizing application processes, quality control, and marketing. The tests required and the interpretations made vary as widely as the questions posed. The evaluation of any antimicrobial test result requires a thoughtful and basic understanding of microbiology, understanding the strengths and limitations of each test, and understanding the mode of action of the antimicrobial agent in question.

BIOPROTECT Antimicrobial treatment on woven and nonwoven medical goods, carpeting, textile building materials, and as a broadcast treatment throughout the hospitals has been laboratory and field tested on a wide variety of materials and has proven utility as a broad spectrum antimicrobial.

Microorganisms

Mold, mildew, fungus, yeast, bacteria, and virus (microorganisms), are part of our everyday lives. There are both good and bad types of microorganisms. The thousands of species of microorganisms that exist are found everywhere in the environment, on our garments and on our bodies.

Microorganisms, their body parts, metabolic products, and reproductive parts, cause multiple problems to building materials and furnishings. They are human irritants, sensitizers, toxic -response agents, causers of disease, and simple discomforting agents. Clearly, microorganisms are the most potent pollutants in the indoor environment, on our clothes, and on our furnishings.

Medical care facilities, schools, hotels, residences, food storage areas, and manufacturing facilities such as electronics, food, pharmaceuticals, and other at-risk material production areas need to have a reaction plan for avoidance and control of airborne and surface sourced microbial contaminants. Strategies for control of microbes must exist for garments, beddings, linens, wipes, surgical fabrics, and other textiles used in healthcare operations and construction materials.

The human symptoms of building sourced microbial exposure involve an array of physical and systemic reactions affecting the skin, mucous

membranes, eyes, upper and lower respiratory tracts and muscles. Some reactions are short-term (acute) and others are long-term (chronic). All affect productivity, health costs, and well-being. Similarly, microbes sourced from textile reservoirs can cause these same effects.

Microorganisms need moisture, nutrients, and most of them need to be associated with a surface. Moisture can come from catastrophic and normal events – a leaky roof, a sweaty pipe, a leaky radiator, condensation on windows, condensation on more subtle surfaces where dew points are reached, humidified air from the HVAC system or any of hundreds other sources. Air conditioners, bathrooms, wall-to-wall carpets, draperies, wall coverings, furniture, bedding and ceiling tiles create ideal habitats for microorganisms. These types of surfaces are found in buildings including offices, hospitals, schools, and homes. Nutrients utilized by microorganisms can be organic material, inorganic material, and/or living tissue. For example, bacteria play an important role as part of the body's microflora, and along with the skin, are shed continuously. Given acceptable growth conditions, they can multiply from one organism to more than one billion in just 18 hours.

The Medical Impact of Microorganisms

The medical impact of microorganisms on an individual depends on genetic heritage, general health, and the physical and mental stress factors in the person's life. Work or other psychological pressures, diet, weather patterns, and environmental pollutants, contribute to the severity of human reactions. For people with a predisposition for respiratory problems - the infirm, elderly, babies, people recuperating from illness, and those being

treated with immunosuppressive drugs, or under unusual stress - the need to minimize contact with microorganisms and other biogenic materials is magnified. Besides these "at risk" people, current research in the U.S., Canada, and Europe, clearly shows that microbial contaminants directly affect the productivity of workers, and that they are a major contributor to the phenomenon known as SBS.

Antimicrobials

The term antimicrobial refers to a broad range of technologies that provide varying degrees of protection for products and buildings against microorganisms. Antimicrobials are very different in their chemical nature, mode of action, impact on

people and the environment, in-plant-handling characteristics, durability on various substrates, costs, and how they interact with good and bad microorganisms.

Antimicrobials are used on textiles to control bacteria, fungi, mold, mildew, and algae. This control reduces or eliminates the problems of deterioration, staining, odors, and health concerns that they cause.

In the broad array of microorganisms there are both good and bad types. Antimicrobial strategies for bad organisms must include ensuring that non-target organisms are not affected or that adaptation of microorganisms is not encouraged. Antimicrobials, when properly applied, limit greatly the life habits and environments for the common dust mite.

Microorganisms cause problems with textile raw materials and processing chemicals, wet processes in the mills, roll or bulk goods in storage, finished goods in storage and transport, and goods as they are used by the consumer. These effects are extremely critical to clean room operators, medical facilities, and food processing facilities. They are also an annoyance and aesthetic problem to athletes and consumers. The economic impact of microbial contamination is significant and the consumer interests and demands for protection is at an all time high.

An Organofunctional Silane Antimicrobial Technology

BIOPROTECT antimicrobial is a molecularly-bonded unconventional technology. The bound unconventional antimicrobial technology, an organofunctional silane, has a mode of action that relies on the technology remaining affixed to the substrate - killing microorganisms as they contact the

surface to which it is applied. Effective levels of this technology do not leach or diminish over time. When applied, the technology actually polymerizes with the substrate making the surface antimicrobial. Durability to wear and laundering with broad-spectrum antimicrobial activity have been demonstrated.

Antimicrobial Function and Adaptation

The unconventional bound antimicrobial stays affixed to the textile and, on a molecular scale, physically stabs (the lipoprotein components of the membrane) and electrocutes (the anionic biochemicals in the membrane) the microorganism on contact to kill it. Like an arrow shot from a bow or bullet shot from a gun, leaching antimicrobials are often effective, but are used up in the process of working, wasted in random misses, or complexed by other chemicals in the environments of use and abuse. Some companies incorporate leaching technologies into fibers and slow the release rate to extend the useful life of the antimicrobial, even adding to them chemical binders and claiming they are now "bound." Whether leaching antimicrobials are extruded into the fiber, placed in a binder, or simply added as a finish to fabrics or finished goods, they all function the same. In all cases, leaching antimicrobial technologies provide a

clearly define the area where the antimicrobial had

it is assumed that the right conditions are present for leaching of a lethal dose at the time that it is needed. The zone of inhibition is the area around the treated substrate into which the antimicrobial chemistry leaches or moves to, killing or inhibiting microorganisms. This killing or inhibiting action of a leaching antimicrobial is witnessed when an AATCC 147 test or other zone of inhibition test are run. These tests are used to measure the zone of inhibition created by a leaching antimicrobial and

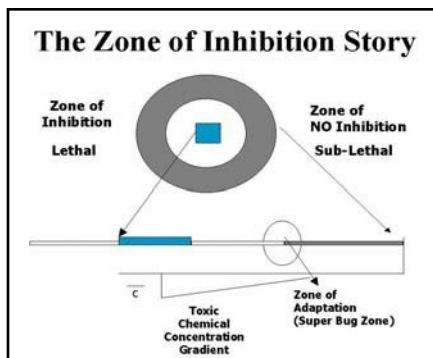
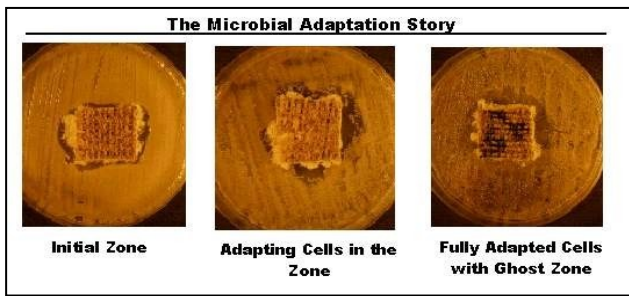


Fig. 2. Wash durability.

killing field or "zone of inhibition." This zone exists in real-world uses if

treated with a leaching antimicrobial. The clear zone



Figs. 3a, 3b, and 3c. The Microbial Adaptation Story.

surrounding the substrate represents the zone of inhibition and the sublethal zone is shown in gray. The area at which the zones merge is presented as the zone of adaptation. Figure 2 shows actual results on the difference between the leaching and the non-leaching antimicrobial treatments on textiles both as first treated and then after five household launderings.

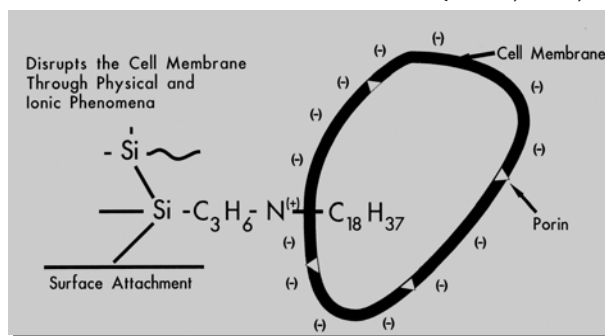
Microbes are living organisms and like any living organism will take extreme measures to survive. Microorganisms can be genetically mutated or enzymatically induced into tougher “super-strains” if they are exposed to sublethal doses (exposed to - but not killed) of an antimicrobial agent. This ability of microorganisms to adapt to potential toxicants has been recognized in the medical community for years. Sublethal levels of antibiotics are generated in patients who discontinue taking antibiotics once their symptoms subside instead of continuing through to the end of the period prescribed by the physician. The exposure of the microbe to a sublethal dose of an antimicrobial can cause mutation of their genetic materials allowing for resistance that is then replicated through the reproductive process creating generations of microorganisms that are no longer affected by the chemistry. This phenomena is of serious concern to the medical community and food processing industries and should be a serious consideration for the textile industry as it chooses the antimicrobials to which it will be exposing the public and their workers.

As with any chemistry that migrates from the surface - a leaching antimicrobial is strongest in the reservoir, or at the source, and weakest the farther it

travels from the reservoir. The outermost edge of the zone of inhibition is where the sublethal dose can be found—this is known as the zone of adaptation (Fig. 1). This is where resistant microbes that have been produced by leaching antimicrobials are found. The ongoing challenge for leaching technologies is the control of the leach rate from their reservoir such that a lethal dose is available at the time that it is needed.

This is demonstrated in the following images from experiments where a microbe sample was taken from the outer edge of the zone of inhibition of a common leaching antimicrobial from treated carpet fiber (Fig. 3a) and used to inoculate a new test plate. This second test plate (Fig. 3b) shows the adapted microorganisms growing within the zone of inhibition. The adapted organism is taken from the second plate and used to inoculate a third plate (Fig. 3c). The microorganism used to inoculate this plate is fully adapted to the leaching antimicrobial and has overgrown the fabric. The ghost zone indicates the organism being slowed but not controlled by the leaching toxicant. All this occurred within just two generations of the test organism under these test conditions.

A significantly different and much more unique antimicrobial technology used in the nonwovens and building construction industries does not leach but instead remains permanently affixed to the surface on which it is applied. Applied in a single stage of the wet finish process, the attachment of this technology to surfaces involves two means. First and most important is a very rapid process, which coats the substrate (fabric, fiber, etc.) with the cationic species



(physisorption) one molecule deep. This is an ion exchange process by which the cation of the silane quaternary ammonium compound replaces protons from water or chemicals on the surface. The second mechanism is unique to materials such as silane

Quaternary ammonium compounds. In this case, the silanol allows for covalent bonding to receptive surfaces to occur (chemisorption). This bonding to the substrate is then made even more durable by the silanol functionality, which enables them to homopolymerize. After they have coated the surface in this manner, they become virtually irremovable,

even on surfaces with which they cannot react covalently (Fig. 4).

Once polymerized, the treatment does not migrate or create a zone of inhibition so it does not set up conditions that allow for adapted organisms. Because this technology stays on the substrate, it does not cross the skin barrier, does not affect normal skin bacteria, nor causes rashes or skin irritations. This organofunctional silane technology has been used for over two decades to treat surfaces from leather and foams to virtually all types of fabrics and is not consumed by the microorganism. It does not poison the microorganism. When a microbe contacts the organofunctional silane treated surface of the fabric, the cell is physically ruptured by a sword-like action and then electrocuted by a positively charged nitrogen molecule (Fig. 5). This antimicrobial technology has been verified by its use in consumer and medical goods including socks, surgical drapes, and carpets in the USA, Asia, and other areas in the world. This technology has been used for nearly twenty-five years

without any human health or environmental problems inside manufacturing facilities or in actual end use situations.

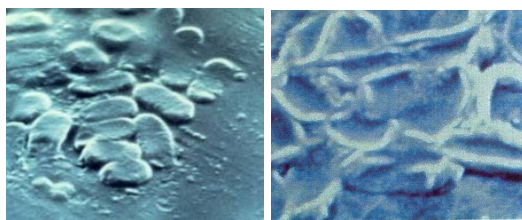


Fig. 5. Healthy and ruptured microorganisms.

Application Methods

Antimicrobial technologies are, as described above, quite varied as are the demands for application. Depending on the technology, the intended end-uses, and the mode of antimicrobial activity, one or another application point and procedure are favored. Adding to the fiber polymer melt to the fiber during processing or to the fabric or finished goods, are all available alternatives.

Addition to the polymer melt is fraught with problems that must be evaluated if this application point is being considered. The performance challenge presented by creating a toxicant reservoir inside of a fiber when the contact with the microbe will be on the surface is dependent on the solubility constant of the antimicrobial, the way that it is embedded into the polymer matrix, the chemicals ability to move in the polymer matrix, and the nature of the environment around the fiber during use.

Other challenges revolve around the need for uniform mixing and subsequent dose release of antimicrobial changes in fiber properties, negative effects on color or reflectance, blocking of process filters, build-up on process equipment, odor fuming, efflorescence or surface salting problems, or chemical conversion problems.

considering probable process temperatures of 230°C for 2-3 minutes. Also concerning is the health and environmental issues for personnel, users, and their environment. Cost of such a strategy must be considered because of the need to use levels of chemical in the reservoir suitable for providing a useful and effective dose during the life of the end-use product.

After a polymer is extruded into the fiber form, antimicrobials can be added with the drawing oils or spin finishes. This method has many merits if the issues of compatibility and uniformity can be solved and that properties of the spin finish are maintained. The fiber treatment must also be able to survive all of the downstream processing without interfering with the fiber processing or present any hazards to the workers, process equipment, or the environment.

In a similar fashion and with all of the same cautions, the antimicrobial treatment may be able to be added in one of the post drawing processing points. Adding at the crimper with or without the crimper oil can take advantage of the heat setting process to assure curing and durability of the antimicrobial binder or, in the

case of BIOPROTECT's reactive silane antimicrobial enhance the bonding reactions needed to maximize durability.

Some antimicrobials, as reactive treatments or ones that are in binders, can be added to a spun bonded product or to the fiber batt by spraying or pad bath. This can be done at the fiber processing plant or as a pre-step at the converters. This method allows for the treatment to be on the surface of the fiber yet still provides all of the needed compatibility and safety properties consistent with the process and end-use. Simple deposition of the antimicrobial, although still practiced by some, is not a good alternative considering increased environmental and human

Antimicrobial Treatment Verification

Another important property of a useful antimicrobial is that its presence should be verifiable. In effect, it is the only way to know that an antimicrobial is really on the product. There is no easy way to tell whether leaching antimicrobials are present on a product. The only known verification technique for a leaching chemistry is to use exacting laboratory tests, which take days or weeks to perform.

Safety Profile

It is critical to review all uses of chemicals used in textiles in light of the intended use and the toxicological profile of the chemical. This is especially relevant as one remembers that antimicrobials, by definition and function, inhibit and/or kill living things. The mode of biological involvement needs to be fully understood so that a proper balance between risks and benefits can be made. For illustration, the following safety profile on BIOPROTECT's Antimicrobial can be considered a minimum profile of needed data for qualifying antimicrobial treatments for use on textiles.

The ability of the silane quat, when properly applied, to chemically bond to the textile substrate and still provide for the broad-spectrum control of microorganisms, makes it well suited to the safety challenges encountered in the full range of applications used in the medical industry.

The following studies have been conducted with the silane quat: (a) acute oral, (b) acute ocular, (c) acute and subacute dermal, (d) acute vapor inhalation, (e) primary skin sensitization and irritation, (f) sub-acute

sensitivities as well as concerns over sublethal antimicrobial doses allowing for microbial adaptation.

A final alternative is adding the antimicrobial on the final textile substrate. This can be done with spraying technology, with a pad bath or exhaust treatment processes. Foam applications have also been used effectively with BIOPROTECT reactive silane antimicrobial onto nonwoven batts or woven textile flat goods. Again, all of the needed compatibility and safety properties consistent with the process and the end-use must be assured.

With the bound antimicrobial technology though, a simple staining test can be performed in a matter of minutes at the mill or in a store to verify proper treatment of a fabric or other surface. This is a very important part of a quality assurance program that gives the manufacturer, the retailer, and the consumer confidence that a feature, normally invisible to the senses, can be seen and is actually on the product providing the protection for which they have paid.

vaginal irritation, (g) four-day static fish toxicity, (h) teratogenic evaluation, (i) sub-acute human wear test (socks), (j) human repeated insult patch test, (k) in-vitro Ames Microbial Assay with and without metabolic activation, (l) in-vitro mammalian cell transformation in the presence and absence of exogenous metabolic activation, (m) in-vitro Host-Mediated Assay and (n) a percutaneous absorption study. Although certain handling cautions are indicated by data from the above tests, no untoward effects are notable regarding treated substrates.

Further to these studies, Olderman reported on studies done by American Hospital Supply (Baxter Health Care), for a surgical drape that had been treated with BIOPROTECT's antimicrobial treatment. These studies included the following pre-clinical biocompatibility tests that are considered appropriate for skin contact medical products: (a) Tissue culture (cytotoxicity), to determine if a tissue culture medium (with serum) eluate of the test material can induce a cytopathic effect on monolayers of human (WI-38) cell, (b) Acute systemic toxicity to evaluate the

potential of a single injection of an extract of the test material to produce a systemic toxicity response, (c) Intracutaneous irritation to evaluate the potential of a single injection of the test material extract to induce tissue irritation, (d) Eye irritation to determine the response of the rabbit eye to the instillation of specific extracts of the test material, (e) Hemolysis to determine if a substance can be extracted from the material which is capable of inducing hemolysis of human red blood cells, (f) Human Repeated Patch Test to determine if the test material is capable of inducing skin irritation and sensitization under controlled patch test conditions and (g). Extensive leachability studies to evaluate the durability and non-leaching potential of the chemically modified fabric

Performance

With an understanding of microbial pests and antimicrobial technologies, we can begin to fit solutions into problems. Medical fabrics are used in a vast array of end-uses in the medical community and have an unlimited number of untapped uses available. These woven, nonwoven, and composite fabrics can be greatly enhanced by the use of the proper antimicrobial agents.

Among the many challenges faced in choosing the right antimicrobial technology for the nonwovens, wovens, or composite fabric industry for medical applications include:

- **Durability:** Durable fabrics need durable features. End-uses of fabrics engineered for use in medical facilities must have antimicrobial treatments that can survive abrasion, sterilization, wet/dry cycles, freeze/thaw cycles, alcohol rinse, and other physical and chemical stresses.
- **Waste Control/Toxicity:** Antimicrobials control a range of microbial pests but in their use must be chosen and engineered so that they do not affect good and helpful microbes. Although heavy metals have long been rejected where they come into contact with the environment or human skin contact, silver-based products have unexpectedly made a resurgence.

Boundless Utilities

Engineering the right antimicrobial usage requires a thorough understanding of the end-use and subsequent use and abuse of the finished goods. In the

when exposed to copious amounts of physiological saline, water and simulated human sweat.

The final results of these biocompatibility studies from the Olderman report indicated that the BIOPROTECT Antimicrobial treated fabric is non-toxic, non-irritating and non-sensitizing to human skin, and has a permanent antimicrobial capacity that cannot be extracted in use. These pre-clinical studies provide sufficient information to allow us to predict the biocompatibility of the finished products and support their safe clinical use. As such, the treated fabric was considered safe for use in surgery. Years of clinical use with no untoward effects also support the suitability of the treated fabric for its intended use.

- **Spectrum of Activity:** Many materials are antimicrobial at the right concentration but in healthcare applications it is very important to have as broad of spectrum of activity as is safe and functional. When integrating antimicrobial treatments into durable goods, this is even more important. A broad spectrum antimicrobial will have activity at the deliverable concentration or contact concentration that kills or inhibits Gram (+) bacteria, Gram (-) bacteria, yeast, and mycelial fungi. Added spectra could include algae, virus, or other microbial pests. Ever more, specialized chemistries have activity against tuberculosis, other pathogenic organisms, or microbial spores.
- **Adaptation:** Any soluble agent that affects a microorganism's life has the potential to set up conditions where the microbial cells adapt or mutate into resistant types. This is bad in almost all settings but clearly should not be tolerated in a medical facility. Use of standard disinfectants or sanitizers call for a rinse after the desired contact time. This is to minimize the risks associated with sub-lethal levels of the antimicrobial being present and risking adaptation or other forms of resistance.

medical industry, industrial fabrics have proven and potential utility in a wide array of end uses. With the infrastructure in place to design and produce the

variety of fabric materials used in industrial fabrics, the industry has the tools and products to fit many needs in the medical marketplace.

- **Construction Materials:** Roofing and envelope materials integrated with the engineered textiles can offer installation and performance properties that make them a preferred choice over any alternatives. Antimicrobial treatments enhance the value of these products.
- **Finishing Materials:** Engineered textiles have a tremendous potential as components of ceiling, wall, and flooring structures. Their use as awnings, tarps, and tents are well integrated into medical facilities as functional and decorative materials. These aesthetic and functional materials all benefit from antimicrobial treatments.
- **Furnishing Materials:** As components of upholstered furniture, bedding, or carpeting, engineered fabrics have a unique role to play and strengthen their value with antimicrobial treatments.
- **Housekeeping Goods:** From wipes, mops, sponges to other cleaning supplies, engineered fabrics have utility and with an antimicrobial finish, serve a more durable and functional life.
- **Garments:** Engineered textiles bring strength, cleanability, breathability, insulation properties, barrier properties and antimicrobial treatments as valuable assets to many uses. These properties are all important in the great variety of garments used in medical care operations.
- **Central Storeroom Materials:** Bedcovers, linens, wraps, drapes, covers, and other textile or film-like materials can all be made and made better with engineered fabrics. The mix and value of properties of nonwoven, woven, and composite fabrics are a certain opportunity for engineered fabrics with antimicrobial treatments.

Successful Applications

The SiQuat technology is used on a variety of woven and nonwoven textiles used in medical facilities. Fenestrations of surgical drapes, mayo stand covers, uniforms, sponges, and linens are among the products that take advantage of the safety profile and antimicrobial effectiveness of BIOPROTECT's Antimicrobial Technology.

These treatments not only provide protection from microorganisms they also add aesthetic and emotive values to a full range of products. Deterioration, defacement, odors, and "harboring" medically

significant microorganisms, are all dramatic effects we see in buildings and products where microbial contamination is present. The ability to make surfaces and nonwovens, wovens, and composite fabrics resistant to microbial contamination has advantages and values in many applications and market segments served by the industrial fabrics industry.

Some examples of successful use of this technology under the predictable abuse found in the medical industry include:

Hospital Blankets³

ViaClean Technologies participated with Spartan Mills and the Virkler Company in studying blankets that were treated with BIOPROTECT antimicrobial technology and blankets that were untreated. In any environment, blankets can become a haven for bacteria. These bacteria usually represent a spectrum of Gram positive and Gram negative organisms capable of producing infections, staining, deterioration and odors. In a hospital environment, fever and sweat

are common and an excellent source of bacterial contamination. In an effort to evaluate the effects a hospital environment has on treated and untreated blankets two separate studies were undertaken. The first simulation study was initiated to simulate the types of exposures blankets receive when in use on a feverish patient. The second in-use study was initiated to determine the effectiveness of the antimicrobial on blankets when stored and used within a care facility.

Summary

The In-use study on Spartan Mills blankets correlates well with the simulated study undertaken earlier in the year. Both studies clearly show that blankets protected by BIOPROTECT's Antimicrobial technology have a significantly lower bioburden and will present less of a risk in the patient environment. Historical data generated by American Hospital Supply and Dow Corning Corporation supports these findings.

These data generated by university, medical and industrial laboratories represent some of the most extensive microbiological work ever performed on antimicrobial treated substrates for use in the medical

community. The control of the microorganisms is impressive and provides numerous benefits.

- Prevents blanket staining due to mold and mildew growth that occurs on damp blankets prior to laundering.
- Controls blanket deterioration due to microbial growth that occurs on blankets during storage.
- Controls odors caused by bacteria and fungus normally found in blankets.
- Provides 3 times more protection from bacteria and fungus than an untreated blanket.

Nonwoven Surgical Drapes⁴

A considerable body of microbiological efficacy data was generated to support the effectiveness of the nonwoven surgical drape through a variety of microbiological tools. These included: in-vitro tests, Scanning Electron Microscopy (SEM) work, and clinical evaluations. The purpose of these tests was to support claims relating to the reduction of microbial dose on the drape in the vicinity of the wound. The surgical drape fabric was found to kill the bacteria

commonly associated with surgical wound infections and takes an active role in maintaining an aseptic field at the wound site. The antimicrobial surface serves to isolate the wound from bacterial transfer from the drape surface. The antimicrobial component of this fabric was chemically bonded, safe for use in surgery, and did not lose its effectiveness when sterilized, stored, or handled during the manufacturing procedure or in surgery.

TABLE I
Results
AATCC Method 100, Antimicrobials on Fabrics¹
BIOPROTECT Antimicrobial Agent Treated

Microorganisms	Sample	Percent Reduction
<i>Staphylococcus aureus</i> Gram (+) Bacteria	Control	16
	Treated ²	100
<i>Escherichia coli</i> Gram (-) Bacteria	Control	0
	Treated	99.6
<i>Klebsiella pneumoniae</i> Gram (-) Bacteria	Control	0
	Treated	100
<i>Saccharomyces cerevisiae</i> Yeast	Control	0
	Treated	99.9

¹ DuPont FC-170 surfactant used, substituted for Rohm and Haas Triton X-100

² Fabric was Kaycel

**Table II
Results
Clinical Isolate Control²
Antimicrobial Agent Treated Nonwovens**

Microorganisms	Sample	Percent Reduction
<i>Citrobacter diversus</i> Wound Isolate	Untreated ¹	14.3
	Treated ¹	93.6
	Inoculum	0
<i>Pseudomonas seruginosa</i> Urine Isolate	Untreated	28.3
	Treated	99.9
	Inoculum	0
<i>Staphylococcus aureus</i> Wound Isolate	Untreated	0
	Treated	99.7
	Inoculum	0
<i>Escherichia coli</i> Urine Isolate	Untreated	11.6
	Treated	98.6
	Inoculum	0
<i>Proteus mirabilis</i> Wound Isolate	Untreated	0
	Treated	99.5
	Inoculum	0

¹ Sontara Fabric
² ASTM E-2149-01

**Table III
Results
Fluid Compatibility Tests
Antimicrobial Agent Treated ISO-BAC Fabric**

Percent Reduction¹ with 15 min. Contact

Sample	Buffered Phosphate	Saline	Serum
Untreated Linen	8	0	0
Untreated Sontara Nonwoven	0	0	0
Treated Sontara	99+	90+	90+

¹ Modified AATCC method 100 using test fluids *Klebsiella pneumoniae* statistically significant at the 95% confidence level.

Wound Care Dressings

The Department of Pediatrics at the University of Bologna evaluated the effectiveness of a special silk fabric (MICROAIR DermaSilk treated with BIOPROTECT) in the treatment of young children affected by AD with acute lesions at the time of examination. Using the SCORAD index, a significant decrease in AD severity was noted with the treated dressings (mean SCORAD decrease from 43 to 30: $P = 0,003$). This allowed for the conclusion that such treated clothes (dressings) should be useful in the management of AD in children.

Carpeting Case Study⁶

An aqueous solution of the BIOPROTECT Antimicrobial SiQuat was applied to dry carpeting in accordance with the manufacturer's specifications. Carpeting was not cleaned prior to antimicrobial applications.

Building occupants in 6 of the buildings were not aware of any remediation activities. Although samples were performed during normal work hours, application of the treatment was performed at night or on weekends without their knowledge.

The pre and post treatment retrieval averages are reported in Table 1. These averages are derived by dividing the total number of colonies retrieved by the number of plate sites.

The variances between pre-treatment and post-treatment retrieval averages range between 71 and 98%. Within this group of buildings, 2 (20%) showed greater than 90% change, 9 (90%) greater than 80% change, and 10 (100%) greater than 70% change.

The actual retrieval counts at 33 sites within a test building are representative of patterns observed in the 10 buildings in this study. The pre-treatment variances range from 2 CFU/plate to 156 CFU/plate whereas the post-treatment retrieval counts range only from 0 CFU/plate to 4 CFU/plate. This stabilization of the aeromicrobiological retrievals is noteworthy along with the consistently effective reduction in numbers retrieved.

<i>Fungal Retrievals in 10 Buildings Pre-and Post-</i>										<i>Antimicrobial Treatment</i>
	1	2	3	4	5	6	7	8	9	Building 10
Pre-Tr., CFU/Plate	13.4	28.0	54.0	40.2	32.0	20.3	36.0	26.0	27.4	17.0
Post-Tr., CFU/Plate		1.7	8.0	1.0	1.4	4.8	3.5	4.1	4.0	3.3 2.9
Variance	87%	71%	98%	95.5%	85%	83%	89%	85%	88%	83%
No. of Sites	50	29	33	45	20	47	14	30	20	15

Case Study - The Arthur G. James Cancer Center Hospital and Research Institute⁷

The study building is a 12-story comprehensive cancer center and research institute located in Columbus, Ohio. Just prior to its opening in January, 1990, a ruptured water pipe on the 12th floor flooded the building with an estimated 500,000 gallons of water. Ceilings, walls, carpeted floors and upholstered furnishings were either wet or exposed to high humidity.

After assuring that the building's structural integrity had not been compromised, attention focused on restoring the microbiological quality of the building to levels consistent with its intended use, particularly in Bone Marrow Transplant and other areas where immunosuppressed patients would be housed.

Despite high efficiency air filtration, and widespread use of a chlorine-based disinfectant fog throughout the building and its ventilation system, large numbers of fungi and bacteria were retrieved from the air in all areas of the hospital. Large numbers of water-associated bacteria, such as *Acinetobacter sp.*, as well as fungi were retrieved from carpeting.

Prior to the flood, hospital and university researchers had designed a study protocol to investigate the effect of surface modification with silane antimicrobials on infection rates within Bone Marrow Transplant, Hematology and Oncology areas in the hospital. The flood and subsequent microbial contamination preempted the study. But elevator shafts, mechanical and electrical chases) were treated with the organosilicon antimicrobial 3-trimethoxysilylpropyldimethyloctadecyl ammonium chloride (BIOPROTECT Antimicrobial) (6) in water for uniformity and penetration throughout the treatment process.

Results

- Pre-treatment retrievals were in a range of 721 – 2,800 CFU's/m³. Of the 209 sample sites, 122 (58%) sites produced 2,800 CFU's/m³, the upper detection limit of the sampler.
- Post-treatment sampling during the seven months following restoration of the building produced an average of 4.1 CFU's/m³ at 643 sites. Retrievals were in a range of 0-25 CFU's/m³. Of the sample sites, 289 sites (45%) produced 0 CFU's/m³; an additional 231 sites (36%) produced retrievals in a range of 1-5 CFU's/m³.
- The second post-treatment samplings were performed in 1991 at 82 sites randomly selected by floor. The samplings produced retrievals in a range of 0-9 CFU's/m³, with an average retrieval of 0.8 CFU's/m³. 40 sites (48%) produced 0 CFU's.
- The final post-treatment samplings were performed in 1992 at 86 sites randomly selected by floor. The samplings produced retrievals in a range of 0-4.7 CFU's/m³, with an average retrieval of 0.4 CFU's/m³. 56 sites (65%) produced 0 CFU's.
- Each of the 24 Bone Marrow Transplant patient rooms was negative for microorganisms during all of the post-treatment samplings.

The facility is presently free of odor and has a new appearance unaffected by the extensive application of a surface antimicrobial. No fungal nosocomial infections were recorded in this facility during the 30-month study and a post study check after five years. All renovations or reconstruction in the facility were strictly controlled and all newly added or modified surfaces were treated with ÆGIS antimicrobial for five years after the initial treatment.

Summary

The health care industry is challenged with providing the best possible care for their patients and a safe environment for health care workers. Microorganisms are the most prevalent and potent pollutants in the indoor environment and their role as causers and aggravators of disease conditions are well documented.

Control of environmentally sourced microorganisms in a building and on building materials is best accomplished by using design and technologies from the beginning of a building's "life" to its demolition. This includes all of the textile materials used in the "life" of the facility. No place is this more important than in health care facilities. The proven technology with the properties appropriate for use at all stages of a medical facilities "life" is the BIOPROTECT antimicrobial SiQuat . Intervention at the time of construction has been shown effective at reducing exposure and risks associated with microorganisms in bone marrow transplant

units, operating theaters, ICUs, recovery rooms, office areas, and general service areas of medical care facilities. Treatment of fabrics used in all areas have shown the benefits of reducing microorganisms. Reduced odors, staining, and deterioration as well as the real opportunity to enhance product value by reducing reservoirs and amplification sites for problem causing microorganisms improves products and steps towards asepsis. To benefit from the demands for antimicrobial/antibacterial products as well as the antimicrobial/antibacterial performance needs of the medical products world, manufacturers have a choice. In choosing, they should utilize a treatment that provides for a microbial control claim and an antimicrobial finish for their textile products consistent with their claims and the needs of their target consumers. This selection should be done by considering the following:

1. Adopting a non-leaching antimicrobial that doesn't pose the risk of crossing the skin barrier or negatively affecting the normal microbial flora of the skin. If it creates a "zone of inhibition" or must integrate into the all to have function, it leaches or moves and has the potential to cause problems to people and the environment.
2. Adopting an antimicrobial technology with a proven history of use. This will help shorten the timelines in bringing products with an antibacterial/antifungal/odor-reducing, antimicrobial feature to market.
3. Adopting an antimicrobial technology that is adaptable across many utilities and stand up to use and abuse conditions through the life of the good.
4. Adopting a non-leaching antimicrobial that doesn't pose the risk of creating adaptive resistant microorganisms.
5. Adopting an antimicrobial technology that is registered with the EPA, the EU, and other regulatory agencies for the specific product it is applied to.
6. Adopting an antimicrobial technology that can be tested for proper application at the mill or at the retailers. A verifiable quality assurance program should be a key component of any application process.
7. Adopting an antimicrobial technology that has technical and marketing support.

General References

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