

**PreventX 24/7 DURABLE SURFACE PROTECTION:
THEORETICAL, LABORATORY & FIELD EXPERIENCE
DURABILITY & ANTIMICROBIAL EFFICACY:
A HEALTHCARE PERSPECTIVE**

INTRODUCTION

Everyday, hospitals and healthcare systems are charged with controlling microorganisms and the negative effects they cause. Deterioration, staining and odors are all dramatic effects that microbial contamination imposes on such medically significant surfaces from uniforms and medical non-woven fabrics to medical devices and hard surfaces including walls, tables, ceilings and air duct systems. Most significantly, these surfaces can harbor microorganisms act as microbial "harbors and transfer site (vectors)," offering ideal environments for the proliferation and spread of microorganisms that are harmful to buildings, textiles and humans. An October 2007 article from The Journal of the American Medical Association estimated, "94,360 invasive MRSA infections occurred in the United States in 2005" which were "associated with death in 18,650 cases."¹

Despite the many precautions and valiant efforts taken by healthcare professionals to prevent or reduce transmission of harmful organisms in hospitals, the risk of cross contamination from hard and soft surfaces to patients and staff is considerable. The only effective strategy for reducing such infections and the conditions where organisms can build resistance is to reduce the dose of microorganisms throughout the healthcare complex. This can be done using a safe and persistent antimicrobial technology to treat such surfaces along with maintaining the highest standards of hygiene and use protocols for antibiotics.

This document discusses how a chemically bonded organofunctional silane antimicrobial has been and can be successfully used to reduce microbial dose on multiple substrates in a healthcare setting, i.e., medical nonwovens, blankets and linens, wound care materials, uniforms and the hard surfaces that enclose and protect the healthcare environment. Laboratory and field test data will be discussed.

MICROBIAL PROBLEMS

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

Human reactions 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. All affect productivity, health costs and well-being. Similarly, microbes sourced from textile surfaces or reservoirs can cause these same effects.

It is imperative that healthcare facilities 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

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, durability on various substrates, costs and how they interact with good and bad microorganisms. Antimicrobials are used on textiles and building surfaces 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.

Some antimicrobial 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 “bound.” No matter where leaching antimicrobials are added to fiber they all function the same. In all cases, leaching antimicrobial technologies provide a killing field or “zone of inhibition.” The zone of inhibition is the area around the treated substrate into which the antimicrobial chemistry leaches or moves to, killing or inhibiting microorganisms. 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 phenomenon is of serious concern to the healthcare community as sub-lethal doses of the leaching antimicrobial can cause target microorganisms to mutate into tougher “super-strains.” This should be a serious consideration for the medical industry as it chooses the antimicrobials to which it will be exposing the public and their workers.

PreventX 24/7 DURABLE SURFACE PROTECTION

A significantly different and unique antimicrobial technology used in the textile and building construction industries does not leach. Instead this antimicrobial remains permanently affixed to the surface on which it is applied.

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. Once applied to the surface, the PreventX 24/7 technology does not migrate or create a zone of inhibition, thus not setting up conditions for organisms to adapt and mutate. Because this technology stays bonded on the substrate, it will not cross the skin barrier, will not affect normal skin bacteria and will not cause skin irritations. Effective levels of this technology do not leach or diminish over time. When applied, the technology actually polymerizes with the substrate making the surface itself antimicrobial. Durability to wear and laundering with broad-spectrum antimicrobial activity have been demonstrated.

The PreventX 24/7 technology has been verified through its extensive use in consumer and medical goods including socks, surgical drapes and carpets in the US, Europe, Asia and other areas of the world. For over thirty years, the PreventX 24/7 technology has been used by consumers and manufacturing facilities without any human health or environmental problems. Numerous patents and peer reviewed and trade industry publications support the efficacy and utility of this antimicrobial technology. Numerous studies have been done for EPA registration, quality control, field efficacy and customer run validations.

LABORATORY & FIELD EXPERIENCES

Case Study – The Arthur G. James Cancer Center Hospital and Research Institute²

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 area 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 the Bone Marrow Transplant, Hematology and Oncology areas in the hospital. The flood and subsequent microbial contamination preempted the study. But, investigation of various antimicrobial systems to achieve sustained microbial control during the study provided an important tool for use in remediation and beyond.

All accessible interior surfaces (including carpeting, ceilings, walls, above ceiling space, furnishings, elevator shafts, mechanical and electrical chases) were treated with the organosilicon antimicrobial 3-trimethoxysilylpropyldimethyloctadecyl ammonium chloride (PreventX 24/7 technology) in water in accordance with the manufacturer's application specifications. The applications were randomly tested for uniformity and penetration throughout the treatment process.

Results (See Table 1)

- ◆ 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 bound PreventX 24/7 technology for five years after the initial treatment.

Table 1

Location		Pre-Treatment	1990	1991 M-1 01 ¹	M-3 03 ²	1992 M-1 01	M-1 03
Total Building	Average: Sites:	2,655.2 209	4.1 643	1.8 83	0.8 82	0.7 105	0.4 86
Ground Floor	Average: Sites:	2,708.8 29	2.7 76	2.7 7	1.0 7	1.0 7	0.3 7
1 st Floor	Average: Sites:	2,614.0 14	16.0 76	1.0 7	0.6 7	1.0 7	0.7 7
2 nd Floor	Average: Sites:	2,642.3 19	0.9 72	1.1 7	0.8 7	1.3 7	0.9 7
3 rd Floor	Average: Sites:	2,691.9 20	4.8 48	1.0 10	0.6 10	0.3 24	0.3 8
4 th Floor	Average: Sites:	2,658.4 22	1.6 68	0.6 11	0.4 11	0.7 13	0.3 11
5 th Floor	Average: Sites:	2,618.0 9	2.1 19	2.0 7	1.2 7	0.5 7	0.1 7
7 th Floor	Average: Sites:	2,758.0 12	4.7 40	2.3 7	0.5 7	0.4 7	0.0 6
8 th Floor	Average: Sites:	2,640.6 17	1.2 58	1.1 7	0.5 7	0.4 7	0.0 7
9 th Floor	Average: Sites:	2,627.0 19	0.8 61	N/D 0	N/D 0	0.8 7	0.2 7
10 th Floor	Average: Sites:	2,608.0 17	1.3 48	1.6 7	0.5 7	0.9 7	0.9 7
11 th Floor	Average: Sites:	2,619.6 13	4.5 36	0.9 8	1.1 7	1.1 7	0.8 7
12 th Floor	Average: Sites:	2,633.6 18	6.3 43	7.0 7	2.3 7	0.8 7	0.2 7

**Commercial Building Studies
- Building Codes -**

BUILDING EVALUATION - COMMERCIAL

STUDY³Ten buildings, representing a wide array of structures and geographies were studied. The common thread is the widespread reporting of SBS symptoms from the building occupants. Suspecting microbial involvement sourced from the environmental surfaces, microbial retrievals and mediation were undertaken. This study was designed to determine gross variances of

Number	Type	Location
1	School	Alexandria, KY
2	Print Shop	St. Petersburg, FL
3	Office Building	Rochester, NY
4	Condominiums	Keystone, CO
5	Office Building	Clearwater, FL
6	Office Complex	Clearwater, FL
7	Office Building	Clearwater, FL
8	Office Building	Miami, FL
9	Office Building	Tampa, FL
10	Office Building	Cincinnati, OH

bioaerosol presence within large test areas.

Gravitational sampling was utilized to provide broad aeromicrobiological profiles of test zones, **Table 3** thereby enabling a quantification of retrievals prior to the following treatment.

Treatment: PreventX 24/7 technology was applied to dry carpeting in accordance with the manufacturer's specifications. Carpeting was not cleaned prior to applications. Building occupants in six of the buildings were not aware of any remediation activities. Although samplings were performed during normal work hours, application of the treatment was performed at night on or weekends without their knowledge.

Testing: Two week prior to treatment, standard plastic petri dishes (BBL) containing Sabauroud's Dextrose Agar were placed at floor level in random arrays (14–50 sites per building) throughout test zones. Plate locations, time, activity and ambient conditions within zones were recorded.

Two week following treatment, petri dishes were placed at floor level in the pre-treatment locations. Post-treatment Samplings were designed to replicate pre-treatment conditions as closely as possible. All plates were exposed for one hour, sealed and sent to the laboratory for incubation and enumeration using standard microbiological methods.

Results: Data and observations are representative of all buildings we have investigated, both in quantification of variances and clinical observations of occupant response. Figure 3 shows the percent variance of each building following treatment of carpeting. 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 71–98%. 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.

In Figure 4 we can see the actual retrieval counts at 33 sites within the test building Number 3. These data are representative of patterns observed in the ten buildings in this study. Note the pre-treatment variances representing a range from 2 CFU/Plate –4 156 CFU/Plate whereas the post-treatment retrieval counts range only form 0 CFU/Plate – 4 CFU/Plate. This stabilization of the aeromicrobiological retrievals is noteworthy along with the consistently effective reduction in numbers retrieved. The clinical profiles of building occupants within the commercial buildings were evaluated during the twelve months following treatment. No changes were reported or observed in any of the buildings. During the second year following treatment, aerobiological samplings were performed at 5 of the buildings in conformance with the initial and post-treatment sampling criteria. The retrieval averages are presented in Table 3 and reveal aeromicrobiological profiles in ranges with post-treatment averages.

Building	Pre-Treatment	Post-Treatment	2nd Year
No. 1	13.4	1.7	3.6
No. 3	54.0	1.0	1.1
No. 6	20.3	3.5	4.1
No. 9	27.4	3.3	3.5
No. 10	17.0	2.9	2.8

In the ten investigations in this report of BRI/SBS within a large diversity of building designs and geographies, symptomatic improvement was uniformly reported room workers and reduction of microbioaerosol levels were observed after treatment of the carpeting with the silane modified quaternary amine. While these data are not conclusive, it challenges us to dislodge traditional perceptions and expand our research efforts to better understand the short and long-term health effect that result for exposure to microbiological pollutants in the workplace.

Figure 1

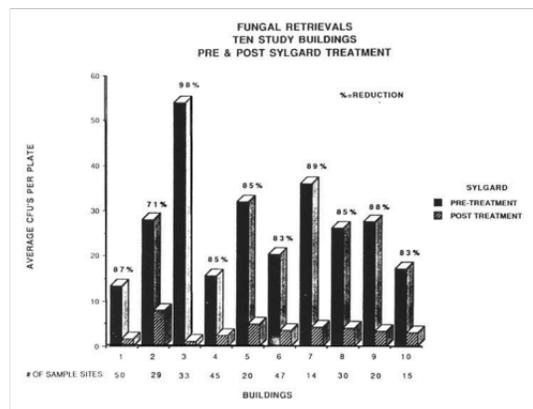
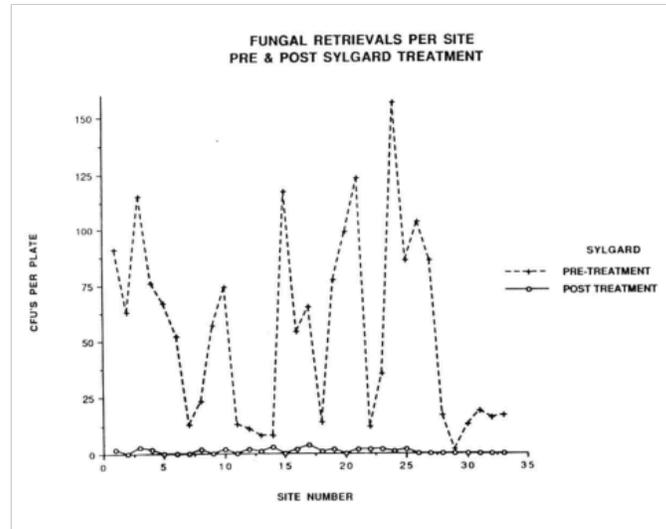


Figure 2



Hospital Blanket Study⁴

MP Environmental participated with Spartan Mills and the Virkler Company in studying blankets that were treated with the bound antimicrobial (PreventX 24/7) 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 treated with the bound 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 healthcare community. The control of the microorganisms is impressive and provides numerous benefits:

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- ◆ 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 Drapes⁵

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.

Carpeting Case Study¹⁰

An aqueous solution of the PreventX 24/7 SiQuat technology 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.

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.

Permanent, non-leaching antibacterial surface-2: how high density cationic surfaces kill bacterial cells¹¹

Rational controlled synthesis of poly(quaternary ammonium) compounds has been used to prepare antimicrobial polymer brushes on inorganic surfaces. The systematic variation of several structural parameters of the polymeric brushes allowed us to elicit the minimum surface requirements and a probable mechanism of action for Escherichia coli cell kill. Polymeric brushes were prepared by surface-initiated atom transfer radical polymerization of 2-(dimethylamino)ethyl methacrylate (DMAEMA), a method that allows the molecular weight of the polymer chains to be precisely controlled as they grow from the target surface. The tertiary amino groups of the polyDMAEMA were then quaternized with alkyl bromides to provide a surface with antimicrobial activity. Dry layer thickness of the polymer brushes was controlled by polymerization time and/or initiator density on the surface. This tunability of surface structure allows the antimicrobial polymer brushes to be tailored rationally. A combinatorial screening tool was developed to elucidate the role of chain length and chain density on cell kill in a single experiment. The results indicate that surface charge density, is a critical element in designing a surface for maximum kill efficiency. The most biocidal surfaces had charge densities of greater than $1-5 \times 10^{15}$ accessible quaternary amine units/cm². The relevance of this finding to the mechanism of action is discussed.

Evidence of a charge-density threshold for optimum efficiency of biocidal cationic surfaces¹²

The deposition of organic monolayers containing quaternary ammonium groups has been shown by many authors to confer biocidal properties on a large variety of solid surfaces. In a search for the controlling factors, the authors have grafted quaternized poly(vinylpyridine) chains on glass surfaces by two different methods and varied the charge density within the organic layer between 10(12) and 10(16) positive charges per cm². The measurements show that this parameter has a large influence on the killing efficiency. Bacterial death occurs in less than 10 min in the quiescent state above a threshold value. The value is smaller for bacteria in the growth state. It also depends on the bacterial type. An electrostatic mechanism based on the exchange of counterions between the functionalized cationic surface and the bacterial membrane is proposed and appears consistent with the results.

Adherence of oral streptococci to an immobilized antimicrobial agent¹³

An antimicrobial agent, 3-(trimethoxysilyl)-propyldimethyloctadecyl ammonium chloride, was immobilized on silica. Interaction between the material (termed) OAIS) and various oral bacterial species were then studied. Seven species of Streptococcus and two Actinomyces were investigated for their ability to adhere to this biomaterial. Cell-surface hydrophobicity and

zeta-potential were examined as well. Analysis of extracted hydrophobic proteins which adhered to OAS revealed that the adherence of these micro-organisms was closely related to the hydrophobicity of their cell surfaces. The results of zeta-potential assays indicated that negative charge on the cell surface inhibited adherence to OAS. Gel electrophoresis revealed that OAS could absorb cell-surface hydrophobic proteins from all bacterial species tested. Preadsorption of hydrophobic components on the cell surface inhibited adherence of the *Strep. mutans* strain to OAS in a dose-dependent manner. The results indicate that OAS adsorption of these oral bacteria was dependent on the degree of hydrophobicity of their surfaces. A major component of this adherence was hydrophobic cell-surface proteins.

Effects of quaternary ammonium silane coatings on mixed fungal and bacterial biofilms on tracheoesophageal shunt prostheses¹⁴

Two quaternary ammonium silanes (QAS) were used to coat silicone rubber tracheoesophageal shunt prostheses, yielding a positively charged surface. One QAS coating [(trimethoxysilyl)-propyldimethyloctadecylammonium chloride] was applied through chemical bonding, while the other coating, Biocidal ZF, was sprayed onto the silicone rubber surface. The sprayed coating lost its stability within an hour, while the chemically bonded coating appeared stable. Upon incubation in an artificial throat model, allowing simultaneous adhesion and growth of yeast and bacteria, all coated prostheses showed significant reductions in the numbers of viable yeast (to 12% to 16%) and bacteria (to 27% to 36%) compared with those for silicone rubber controls, as confirmed using confocal laser scanning microscopy after live/dead staining of the biofilms. In situ hybridization with fluorescently labeled oligonucleotide probes showed that yeasts expressed hyphae on the untreated and Biocidal ZF-coated prostheses but not on the QAS-coated prostheses. Whether this is a result of the positive QAS coating or is due to the reduced number of bacteria is currently unknown. In summary, this is the first report on the inhibitory effects of positively charged coatings on the viability of yeasts and bacteria in mixed biofilms. Although the study initially aimed at reducing voice prosthetic biofilms, its relevance extends to all biomedical and environmental surfaces where mixed biofilms develop and present a problem.

Immobilization of octadecyl ammonium chloride on the surface of titanium and its effect on microbial colonization in vitro¹⁵

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The aim of our study was twofold: to immobilize an organosilicon quaternary ammonium salt (3-(trimethoxysilyl)-propyldimethyl-octadecyl ammonium chloride, Si-QAC) on the surface of pure titanium and to investigate the antimicrobial activity of Si-QAC-immobilized titanium against microbial adherence and biofilm formation. The results of ToF-SIMS analysis of Si-QAC-titanium suggested the possibility of immobilizing Si-QAC on titanium surface through Ti-O-Si coupling, and that Si-QAC treatment significantly reduced both the adherence and colonization of *Candida albicans* and *Streptococcus mutans* isolates. The antimicrobial activity was achieved through at least two mechanisms: the first was attributed to the octadecyl alkyl chain which inhibited initial adherence, and the second was attributed to the quaternary ammonium salt which killed initial adherent cells as well as retarded or inhibited subsequent microbial growth. Further, thermocycling did not significantly reduce the antimicrobial activity of Si-QAC-titanium, and no significant cytotoxicity of Si-QAC-titanium was observed in either cell viability test or proinflammatory cytokine production test using human gingival fibroblasts. These results, taken together, favorably suggested that Si-QAC treatment would be a helpful means to inhibit dental plaque or denture plaque formation.

SUMMARY

Reducing dose of microorganisms in the healthcare environment by eliminating reservoirs and transfer surfaces using safe and effective antimicrobial treatments is critical to reducing microbial dose and has been clearly demonstrated with the use of the bound PreventX 24/7 antimicrobial technology on a wide range of substrates and clinical settings.

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 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 adaptative resistant microorganisms.
5. Adopting an antimicrobial technology that is registered with the EPA, the EU BPD 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.

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