Antimicrobial Performance of Medical Textiles

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Introduction

The textile industry is challenged by the presence of microorganisms and the negative effects they cause. Deterioration, defacement and odors are all dramatic effects that occur from the microbial contamination of woven, nonwoven, and composite fabrics. Fabrics can also act as a "harbor" as most offer ideal environments for medically significant microorganisms. The ability to make textiles resistant to microbial contamination has advantages in many applications and market segments. This is especially true in medical markets where engineered textiles have already contributed a degree of aseptic sophistication to historically used materials.

The textile industry is challenged by the presence of microorganisms and the negative effects they cause.

Textiles used in medical applications have unique microbial problems and their control is a complex chemical, physical, and microbiological task. Use of woven, nonwoven, and composite fabrics in the United States' medical community has greatly expanded in recent years as evidenced by the fact that over half of the drapes used in surgery are nonwovens or engineered fabric. The microbiological integrity of textiles 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 with nonwovens and engineered fabrics 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.

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 respitory 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.

Microbes are not as simple as the whole and intact organisms tested in the laboratory. Their somatic parts, reproductive parts, and metabolites, are implicated as potential human or building antagonists.[2] Microorganisms are the only pollutant source that produces all forms of pollutants: particulates, gases, and infectious biologicals. They are particularly potent in that they can amplify and cause the full breadth of discomfort, irritation, sensitization, toxic reaction, and diseases that are associated with indoor environmental quality problems.

This impact of microorganisms demands that we have effective ways to detect them in indoor environments, to determine whether or not they are in balance, and to mitigate and protect against their presence and negative effects

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.

Antimicrobial Finishes

Antimicrobials do not all work the same. The vast majority of antimicrobials work by leaching or moving from the surface on which they are applied. This is the mechanism used by leaching antimicrobials to poison a microorganism. Such chemicals have been used for decades in agricultural applications with mixed results. Besides the challenges of providing durability for the useful life of products, leaching technologies have the potential to cause a variety of other problems when used in nonwovens. These leaching properties can contact the skin and potentially affect the normal skin bacteria, cross the skin barrier, and/or have the potential to cause rashes and other skin irritations. A more serious problem with leaching technologies is that they allow for the adaptation of microorganisms.

An antimicrobial with a completely different mode of action than the leaching technologies is a molecularly-bonded unconventional technology. The bound unconventional antimicrobial technology, an organofunctional silane, the ÆGIS Microbe Shield Treatment, 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. This type of antimicrobial technology is used in textiles that are likely to have human contact or where durability is of value.

The ÆGIS Microbe Shield™ Treatment

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 quaternaryammonium 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

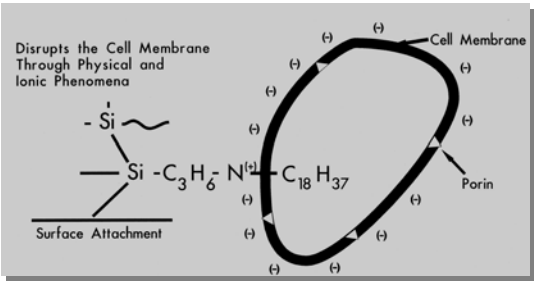

Fig. 1. Bonded chemical.

homopolymerize. After they have coated the surface in this manner, they become virtually irremovable, even on surfaces with which they cannot react covalently (Fig. 1). [1]

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

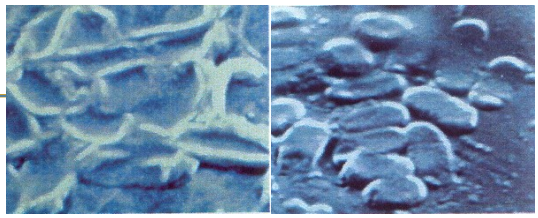

Fig. 2. Healthy and ruptured organisms.

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. 2). 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.

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 the ÆGIS AEM 5700/5772 Antimicrobial can be considered a minimum profile of needed data for qualifying antimicrobial treatments for use on textiles.

The ability of the silanequat, 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 silanequat: (a) acute oral, (b) acute ocular, (c) acute and subacute dermal, (d) acute vapor inhalation, (e) primary skin sensitization and irritation, (f) sub-acute 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 the AEM 5700/5772 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 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 AEM 5700/5772 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.[2]

Performance

With an understanding of microbial pests and antimicrobial technologies, we can begin to fit solutions into problems. Engineered industrial 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 industrial 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.

- **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.

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

Speier and Malek were able to demonstrate the antibacterial, antifungal, antiviral, anti-algal, and anti-protozoal activity of this surface bonded agent against a broad spectrum of microorganisms, even after repeated washings.

- **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.

ÆGIS Technology

In 1969, researchers at Dow Corning Corporation discovered a unique way to attach biocidal agents permanently and directly to a wide variety of surfaces. The resulting non-volatile polymer is unique among antimicrobials in that it does not create a zone of inhibition and does not dissipate over time. This extraordinary technology permits the continuous and durable activity against mildew that is required to prevent infestation. Because

the material does not lose effectiveness through absorption or dissipation, microorganisms have never been shown to develop immunity against it.
This 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 the ÆGIS Antimicrobial.

Speier and Malek were able to demonstrate the antibacterial, antifungal, antiviral, anti-algal, and anti-protozoal activity of this surface bonded agent against a broad spectrum of microorganisms, even after repeated washings. Isquith et al were able to demonstrate by radioisotope analysis and bioassay, that its antimicrobial activity did not result from release of the material and is a surface-associated phenomenon. This is also supported by its lack of a classic zone of inhibition. Thus, chemical reactivity with the cell or its components was not required for activity.[1]

The immobilization of an antimicrobial agent could produce self-sanitizing surfaces that provide significant advantages over conventional approaches to disinfection. Since antimicrobial activity does not involve release of the material, and the material remains present at the same concentration, Gettings was able to show that resistance and adaptation do not occur.[3] This not only extends the predicted activity of the agent, but minimizes the possibility of cross-linked antibiotic resistance, as well. Since the antimicrobial remains chemically bonded to the surface molecules, there is a low potential for irritation, toxic, or other human exposure consequences. The permanent attachment of the antimicrobial to the surface molecule also minimizes the environmental risks associated with conventional antimicrobial usage.

The modification of interior surfaces with a bound antimicrobial agent could prevent the development of microbial reservoirs in a building. The destruction of airborne microorganisms upon contact with antimicrobial surfaces would further reduce human exposure potential, producing an environment with lowered risk of allergenic, infective, or toxigenic consequences for building occupants.

Hayes and White have shown that antimicrobial activity can be imparted to a variety of substrates with this agent and Kemper et al have shown that antimicrobial activation of interior building surfaces with this agent reduces airborne microbial concentration. This potential was further explored to determine the usefulness of this technology in a variety of building conditions, treatment surfaces, and levels and types of microbial contamination.

For the very first time, Dow Corning's new technology made it possible to actually control the growth and development of mildew and other microorganisms on any treated surface – even after repeated cleanings and extended use.

This unique technology, now ÆGIS Antimicrobial, has been widely used and is well reported on for its long-term effectiveness in the control of microbial contamination in indoor environments and an unlimited range of substrates and end use products. Case histories and peer review publications show how this material provides relief and protection from microbial problems.

Successful Applications

The manufacturers and users of consumer and commercial products are challenged by the presence of these microorganisms and the negative effects they cause. Antimicrobial treatments for bacterial, fungal, and mite control, are proving to be popular among consumers, manufacturers, and building operators. 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:

Building Component Treatment After "Flood"

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

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, 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 (ÆGIS™ Antimicrobial) in water in accordance with the manufacturer's application specifications. The applications were randomly tested for uniformity and penetration throughout the treatment process.

Results

- Pre-treatment retrievals were in a range of 721 – 2,800 CFU's/m^3. Of the 209 sample sites, 122 (58%) sites produced 2,800 CFU's/m^3, 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/m^3 at 643 sites. Retrievals were in a range of 0-25 CFU's/m^3. Of the sample sites, 289 sites (45%) produced 0 CFU's/m^3; an additional 231 sites (36%) produced retrievals in a range of 1-5 CFU's/m^3.

- 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/m^3,

with an average retrieval of 0.4 CFU's/m^3. 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.[4]

Zone of Inhibition Test (Table 1)

The zone of inhibition test, when a zone is produced, shows that the antimicrobial is not durable. This increases the risk of toxicological involvement and the risk of mutational or inductive adaptation phenomena being manifested. Although the silanequat does not give a zone of inhibition, encroachment of the test organisms onto the test surface is eliminated. The fungal control demonstrated in Figure 1 clearly shows this benefit as compared to a traditional leaching type of antimicrobial. This fungal activity and durability are well suited for many nonwoven applications. Table I shows typical results from the AATCC-30 Fungicide Test Protocol and further supports this important property.

TABLE I
Results
AATCC Method 30, Fungicides, Evaluation on Textiles
AEM 5700™ Antimicrobial Agent Treated Nonwovens

Percent of Sample Covered[1] After:

Sample	3 Days	5 Days	7 Days
Untreated	20	60	100
Treated Level A	0	5	20
Treated Level C	0	0	0

[1] *Aspergillus niger*

Padding Tests – Table II

The utility of padding type protocols to testing the original silanequat treated barrier fabric seemed appropriate except for the hydrophobic nature of the treated fabric. This introduced considerable error into the testing, and modification of the ATCC-100 antimicrobial test protocol to include sophisticated wetting agents was necessary. Padding tests are useful as an indicator of surface antimicrobial activity but are difficult to run reproducibly and are extremely operator sensitive. Typical results using the AATCC-100 protocol plus re-wetter are shown in Table II.

TABLE II
Results
AATCC Method 100, Antimicrobials on Fabrics[1]
AEM 5700 Antimicrobial Agent Treated Nonwovens

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

[1] DuPont FC-170 surfactant used, substituted for Rohm and Haas Triton X-100
[2] Fabric was Kaycel

Dynamic Shake Flask Test – Table III

To overcome the testing problems associated with the hydrophobic nature of the test surface and yet maintain some linkage to "real world" dynamics, American Convertors, using a modification of the classical rotating tube test, developed a dynamic shake flask test. This test has been modified as follows by Dow Corning: The test utilizes a 150 ml Ehrlenmeyer flask in which 5 ml of a liter of 1 x 10^5 to 3 x 10^5 CFU/ml (as colony forming units) of test organism is added to 70 ml of phosphate buffer or other test solutions and a measured amount of test fabric. This system is then placed on a Burrell Wrist Action Shaker for a representative time period. Zero time and test time control and treated samples are then compared for percent reduction. This method is now ASTM E2149-01 Results from this testing showed that the fabric could be treated durably and uniformly with AEM 5700 and that the fabric was effective against both Gram negative (*Klebsiella pneumoniae)* and Gram positive (*Staphylococcus aureus)* bacteria. Data generated using this test protocol can be seen in Table III. Clinical isolates were used as the test organisms. Note the effective range was from 93.6% - 99.9% reduction for these organisms commonly found in hospital situations. Since the inoculum control showed the organisms to be healthy, one could assume that those organisms that showed reduction with the untreated controls were sensitive to some component of the fabric or were trapped within the fabric and therefore, not recovered.

Table III
Results
Clinical Isolate Control[2]
AEM 5700 Antimicrobial Agent Treated Nonwovens

Microorganisms	Sample	Percent Reduction
Citrobacter diversus	Untreated[1]	14.3
Wound Isolate	Treated [1]	93.6
	Inoculum	0
Pseudomanas seruginosa	Untreated	28.3
Urine Isolate	Treated	99.9
	Inoculum	0
Staphylococcus aureus	Untreated	0
Wound Isolate	Treated	99.7
	Inoculum	0
Escherichia coli	Untreated	11.6
Urine Isolate	Treated	98.6
	Inoculum	0
Proteus mirabilis	Untreated	0
Wound Isolate	Treated	99.5
	Inoculum	0

[1] Sontara Fabric
[2] ASTM E-2149-01

Padding Tests – Table IV and V

As described earlier, various modifications of the AATCC-100 test have been used to demonstrate the effectiveness of the AEM 5700 treated Fabric. Listed in Table IV are results from a fluid compatibility test run using buffered phosphate, saline, and serum. The *K. pneumoniae* microbial dose was added to each of the test fluids and then aliquots were applied to treated and control fabrics. Results were very uniform and confirm that microbial loads from such fluids are readily controlled on the AEM 5700 Treated Fabric.

Table V contains the results of using this test protocol with defibernated blood. The clear value of reducing microbial dose level is illustrated in these results. Whereas neither the linen (A) nor the two untreated nonwovens (B and C) showed any reduction of the test organisms through two hours, the ISO•BAC Fabric showed a 59% reduction in 30 minutes and 72% reduction after two hours. These tests were very rigorous in terms of organic load and microbial load and yet bacterial dose levels were significantly reduced.

Table IV
Results
Fluid Compatibility Tests
AEM 5700 Antimicrobial Agent Treated ISO-BAC Fabric

Percent Reduction[1] with 15 min. Contact

Sample	Buffered Phosphate	Silane	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.

Table V
Results
Surface Testing of Defibrinated Blood and Bacteria
AATCC – 100 Test

Sample (Surface)	Contact Time	#of Organisms	%Reduction
A) Green Surgical Linen	0	8,750	---
	1	9,300	0
	3	8,700	0
	5	8,850	0
	30	9,900	0
	60	10,350	0
	120	10,850	0
B) Nonwoven Table Cover From J&J Laparotomy Pack	0	14,050	---
	1	17,450	0
	3	13,750	2
	5	13,400	5
	30	15,350	0
	60	16,450	0
	120	17,800	0
C) Hi Lift – Untreated Control	0	13,650	---
	1	14,150	0
	3	13,600	0
	5	14,000	0
	30	13,750	0
	60	14,600	0
	120	16,850	0
D) HiLoft with AEM 5700 Agent	0	14,900	---
	1	15,400	0
	3	14,400	0
	5	12,400	0
	30	6,050	0
	60	5,650	0
	120	4,200	0

1. Inoculum: 90% Defibrinated Sheep Block Contaminated with *Klebsiella pneumoniae* ATCC 4352

Conclusion

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 ÆGIS Antimicrobial. 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.

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