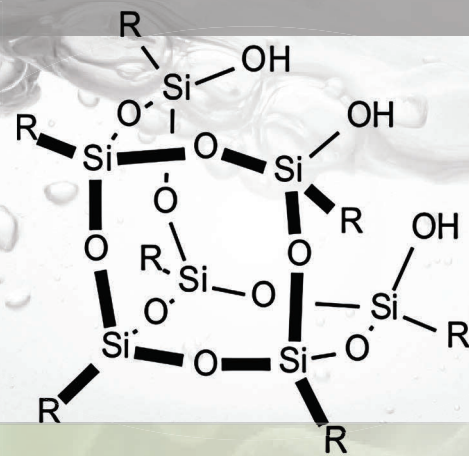




Technical Guide for
Performance and
Regulatory Compliance

BIOSAFE®

Organosilane Antimicrobials



bacteria



fungi



mold



mildew

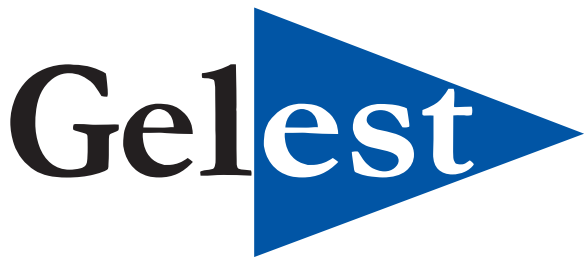


algae

Provides long-lasting surface protection

Gelest

Enabling Your Technology



Enabling Your Technology

Organosilane Antimicrobials

About Antimicrobial Surfaces

Antimicrobial additives for surfaces and textiles perform differently and are regulated differently than sanitizers or disinfectants. Antimicrobial “additives” are considered to be microbiostatic agents that protect products, not people, per EPA regulations. The key distinction is that these are non-health claims.

BIOSAFE is used to protect any material or textile, under its approved uses, to mitigate or stop the growth of product damaging microbes. Key considerations regarding the end-product’s performance include its environment, the wearability of the surface, and the degree of microbial control needed to achieve the product’s purpose.

Breadth of Antimicrobial Applications

When deciding to use an antimicrobial additive, the first thing to consider is the required product performance and how marketing claims will communicate that performance. This is the common starting point for all antimicrobial products. The formula used for a product controlling algae in water lines will differ from the formula controlling either odor-causing bacteria in a



refrigerator gasket or damaging mold and mildew in building materials. The activity of a microbiostatic treatment on a bulk surface or textile, such as BIOSAFE, are verified by standardized industry methods.

Test methods commonly used to determine the antimicrobial activity of solid treated articles are:

JIS Z 2801 - a method where microbes are inoculated onto an antimicrobial surface and covered for 24hrs, and survivors are counted.

ASTM E2149 - a method where the material is immersed and shaken in a microbial solution for 1hr, then removed, and surviving organisms are counted.

Third party verification is available from labs that perform this type of “treated article” testing. Please contact us for recommendations of independent third party labs that are EPA and FDA compliant.

About EPA Regulations

BIOSAFE and other microbiostatic treated products fall under the jurisdiction of EPA and the “treated article exemption”. Before production, a manufacturer must understand the regulatory limitations of a treated object, textile, or liquid as well as the limitations of possible marketing claims. For instance, a yoga mat manufacturer can state the mat is composed of a material that prevents the growth of odor causing microbes and be within regulatory limitations. However, if a yoga mat manufacturer stated that the mat kills 99% of MRSA, then the manufacturer is making a marketing claim that is considered a health claim, which is outside the scope of a microbiostatic agent. Products incorporating BIOSAFE into or onto the surface are operating under the EPA’s “treated article exemption”. The “treated article exemption” removes the necessity for manufacturers using BIOSAFE interface with EPA, provided the manufacturers use BIOSAFE in accordance with the EPA label and the claims center on the protection of the product, not the protection of people. Please Note: EPA regulations can be somewhat nuanced and the interpretation of the rules may change depending on EPA staff perspective. Thus, Gelest encourages verifying regulatory compliance with EPA or EPA consultants prior to sale of their BIOSAFE containing product.

About BIOSAFE

BIOSAFE is a silicon-based antimicrobial that imparts bacteriostatic, fungistatic, and algistatic properties to coatings and resins for manufactured goods. It is available as a powder, solvent or aqueous solutions. With proper integration, BIOSAFE products have high antimicrobial performance in ISO and ASTM testing. The active ingredient in the BIOSAFE Antimicrobial was developed and registered with the EPA in the mid 1970's, and has since been widely utilized in numerous applications for over 35 years. BIOSAFE has expanded the breadth of applications and manufacturing processes by removing the VOC's and making it available in a new polymeric powder. This powder, similar to its solvent-based predecessors, can be formulated into coatings, but unlike its predecessors, the powder can be compounded with polymer resins.

What does BIOSAFE do?

The antimicrobial, when properly incorporated in accordance with the instructions and specifications provided, imparts a protective bacteriostatic, fungistatic and algistatic surface on substrates to prevent deterioration and discoloration caused by fungi, prevent algae growth and inhibits the growth of odor-causing bacteria. It is durable, leach resistant, and non-migrating. It does not create the conditions that promotes the development of resistant microorganism.

Frequently Asked Questions

Q: Does this product have EPA registration?

A: Yes, the active ingredient in BIOSAFE is a patented and EPA registered siloxane polymer EPA Reg. No. 83019-1-4. Coating and treated articles themselves are exempt from registration under 40 CFR 152.25(a) .

Q: How has the BIOSAFE been tested?

A: The antimicrobial effectiveness and safety has been verified by independent GLP/EPA registered labs-

Antimicrobial Effectiveness

ISO 22196:2007

ASTM E-2149-10

Safety Studies

USP Class VI

ISO 10993-1

EPA Acute Toxicity Package

BIOSAFE's antimicrobial effectiveness is verified by ISO and ASTM standards as related to the product and its use.

Q: What can I apply BIOSAFE into/onto?

A: BIOSAFE can be incorporated into or applied on to any hard, non-porous surface, any textile, upholstery, or soft porous good. It's ideal for bulk surfaces and for fabrics that are susceptible to microbial contamination.

Q: How does the BIOSAFE technology work?

A: The active ingredient in BIOSAFE forms a colorless, odorless, positively charged polymer that molecularly bonds to your product's surface. The strong positive charge disrupts the cell membrane of all microorganisms that come in contact with the active surface, thereby causing their cytoplasm and organelles to leak out. It resembles popping a water balloon. Because of this physical kill mechanism, BIOSAFE does not promote the development of drug resistant superbugs.

Microbiology Notation

When reviewing results from microbiological studies it is important to understand the definitions of the terms and scope of the numbers. Results are reported in either percent reduction or scientific notation.

1 log reduction = 90% reduction

2 log reduction = 99% reduction

3 log reduction = 99.9% reduction

4 log reduction = 99.99% reduction

5 log reduction = 99.999% reduction

6 log reduction = 99.9999% reduction

So, if reviewing a study report from a lab indicating a 3.5 log reduction, then you know it corresponds to a percent reduction somewhere between 99.9% and 99.99%. but a 2.5 log reduction does not equal a 99.5% reduction.

Log ---> Percent

$$L = -\left(\log_{10}\left(\frac{-P}{100} + 1\right)\right)$$

Where:

P is the percent reduction

L is the log reduction

Percent---> Log

$$P = (1 - 10^{-L}) \times 100$$

Where:

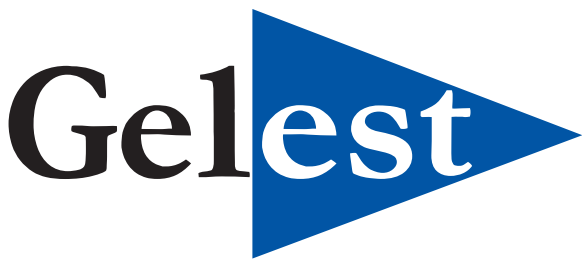
P is the percent reduction

L is the log reduction



 Protected

 BIOSAFE®



Enabling Your Technology

BIOSAFE® Products

HM 4100 ANTIMICROBIAL 84%
 EPA Registration Number: 83019-1 dry powder
 CAS# 199111-50-7 (trihydroxy)
 Application: Resin blending and compounding

HM 4005 ANTIMICROBIAL 5%
 EPA Registration Number: 83019-3 in water
 CAS# 199111-50-7 (trihydroxy)
 Application: Water based surface treatments

HM 4001 RTU ANTIMICROBIAL 0.75%
 EPA Registration Number: 83019-2 in water
 CAS# 199111-50-7 (trihydroxy)
 Application: Water based surface treatments

HM 4072 ANTIMICROBIAL 72%
 EPA Registration Number: 83019-4 in MeOH
 CAS# 27668-52-6 (trimethoxy)
 Application: Water based surface treatments

Safety Studies

These tests were conducted under GLP protocol

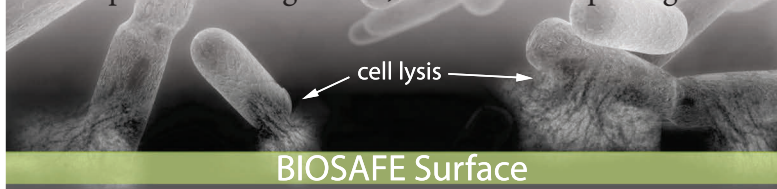
- Cytotoxicity: Agar Diffusion Assay ISO 10993-5*
- Acute Dermal Toxicity OPPTS No. 870.1200*
- Acute Dermal Irritation OPPTS No. 870.2500*
- Acute Eye Irritation OPPTS 870.240*
- Acute Oral Toxicity Study (USP) OPPTS 870.1100*
- Acute Inhalation Toxicity Study OPPTS 870.130*
- Skin Sensitization: OPPTS 870.2600*
- HR IPT- Human Repeat Insult Patch Test: 48 day*
- AMES- Mutagenicity Study*

**all studies are available for review upon request*

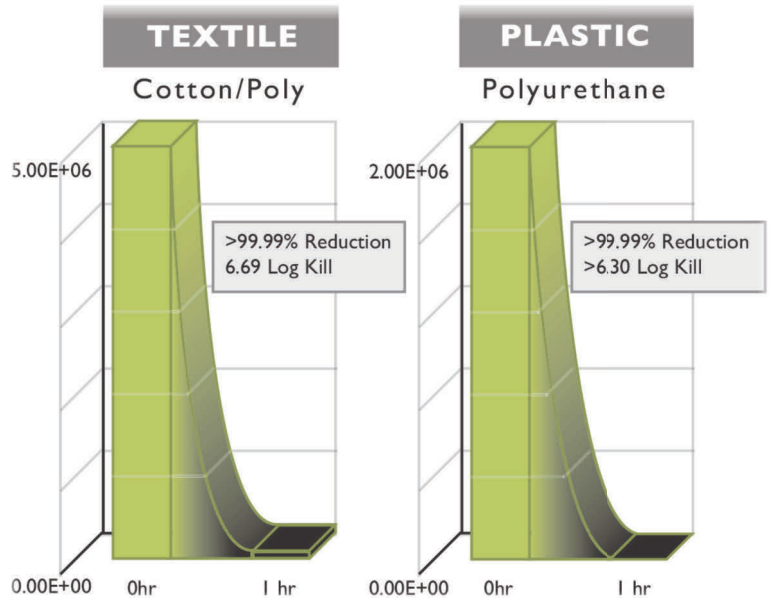
Antimicrobial Effectiveness and Comparison

Products with BIOSAFE properly integrated have high antimicrobial performance in ISO and ASTM testing. Typically, when a product performs with 3-logs (99.9%) or greater it will exhibit bacteriostatic, fungistatic, and algistatic properties in the finished good.

Most antimicrobial technologies are designed to pass through the cell wall and attempt to poison the microbe from the inside by interfering with the microbe's metabolism and altering the microbe's DNA. This may lead to mutation and adaptive microorganisms, i.e. resistant superbugs.



BIOSAFE is not metabolized by the microbial cells, instead it creates a network of electrically charged molecules on the surface, which rupture the cell wall on contact. BIOSAFE creates an invisible coating which bonds to the applied surface and is ready to destroy any microbes that come in contact with the surface. This physical rupturing of the cell wall is a superior way to kill a microbe. It does not promote resistant superbugs and it is not actively leached into the environment or person, as observed with silver or triclosan technologies.



ASTM E-2149-10 against Escherichia coli



ASTM G-21 against black mold fungus

Antimicrobial Fact Sheet

Making choices about which antimicrobial technology to use for your product is not easy. Leaching antimicrobials may claim to be “bound”, “embedded”, or “contained” but they are designed to diffuse and migrate, and therefore are not “chemically bound”. It’s important to understand the facts about modes of action, safety and handling, leaching, and color before choosing your antimicrobial.

BIOSAFE[®]
Silane Based

Silver-Based

Triclosan-Based

	BIOSAFE[®] Silane Based	Silver-Based	Triclosan-Based
Mode of Action	Physically ruptures the cell membrane	Releases ionic free radicals that react with cell DNA and disrupt critical life processes in the cell.	Releases chlorinated phenols and other organic radicals for consumption or cellular absorption, causing lethal mutations
Leaching or non-leaching	Chemically bound, covalent bonding & <i>non-leaching</i>	Embedded and designed to leach out and be metabolized by cells	Embedded and designed to leach out and be metabolized by cells
Cost In-use	Economical	Expensive	Moderate
Adaptive Organisms	Does not promote adaptive organisms	Can create adaptive organisms	Can create adaptive organisms
In-Plant Safety and Handling¹	Mild eye irritation	Harmful if inhaled, harmful if absorbed through skin, moderate eye irritation.	Moderate eye irritation, harmful if absorbed through skin, avoid contact with skin, eyes, or clothing. Do not breathe dust.
Color in Polymers	Does not change product color	Color shifts to brown, gray, and yellow can occur	Does not change product color

Resin Blending and Compounding

The polymeric antimicrobial powder HM 4100 can be dry blended into the bulk resin by any variety of standard mixing operations. The powder will adhere to the surface of the bulk resin particles and become homogeneously mixed. Following mixing the HM 4100 into the host resin, it is ready for molding, extrusion, or other thermoplastic processes to make the finished good. Care should be taken to keep this mixture in a dry environment. In certain resins it is recommended that the mixture be dried before it is used. HM 4100 is hygroscopic and can hold 5% moisture.

Resin Compatibility

TPU- Thermoplastic Polyurethane
Urethane Foam
Polyether block amide (PEBAX®)

Polyamide 6 (PA6 or nylon 6)
Silicone (not post-cured)
Acrylic (cast and thermoplastic)

Acrylic adhesives
Spun fiber (PA6, PE, PP)
Fiberglass Gel Coat

Loading Level

Dependent upon the finished goods requirement for efficacy, one can use between 1 part per thousand to 10 parts per thousand of BIOSAFE to base resin by weight (0.1%- 1.0%). BIOSAFE is dispersed throughout the polymer matrix via blending followed by polymer processing (i.e. thermoplastic, thermoset, etc.)

Temperature

A process temperature of < 170 °C is preferred, but it is time, temperature, and aerobic dependent. BIOSAFE can survive short times at temperatures up to 250 °C if there is little to no oxygen present, as in injection molding or fiber spinning.

Time, Oxygen, and Heat History

BIOSAFE is vulnerable to thermal breakdown: A thermal gravimetric analysis shows the product is stable up to about 250 °C in an inert (i.e. Nitrogen) oxygen-free and water-free environment. In commercial use, time, temperature, and chemical reactivity will affect the stability of BIOSAFE. Additionally the number of heat histories should be minimized. It is preferable to feed the product into an extruder downstream nearest to the die, rather than masterbatch and go through two full heat histories.

Water Based Surface Treatments

Applying BIOSAFE to surfaces can be accomplished by the following sequence: Typical substrate candidates include carpet, apparel, non-wovens, roll goods, building materials, shoes, and indoor environment surfaces.

Agitation

Under constant, mild agitation, pour the required amount of concentrated HM4072 or HM4005 Antimicrobial into a container with a previously determined volume of water

Temperature, pH, and Hardness

At a temperature of about 22°C (75°F), and a pH between 4.5 and 6.5, water should be soft to slightly hard. Upon mixing with water, the antimicrobial is then ready to react with the substrate.

Anionic Residue

It is essential that the antimicrobial finish be applied to a substrate that is clean. CAUTION! Anionic detergents should not be used. Because the antimicrobial functions via its cationic charge, excessive anionic material in the presence of the antimicrobial will decrease its efficacy.

Concentration

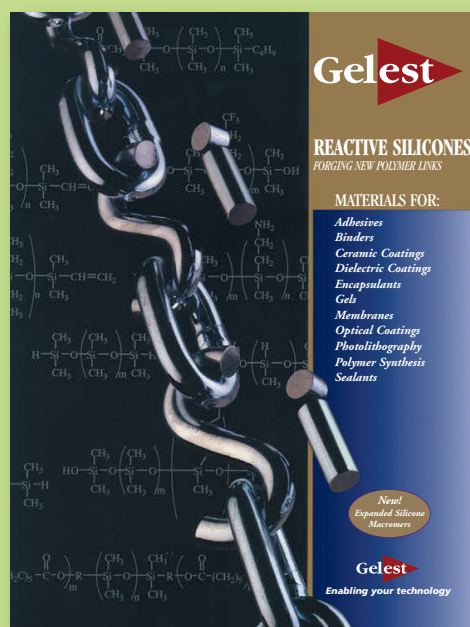
The EPA authorized limits of final application concentrations are from 0.01 to 1.0% of active based upon substrate weight. Most applications are optimized at approximately 0.25-0.5%. Before commercialization, one should thoroughly test any application; optimize concentrations, and independently investigate satisfactory performance. Furthermore, when used in combination with other chemicals (i.e. finishes) testing should be performed to demonstrate proper treatment and compatibility.





Hydrophobicity, Hydrophilicity and Silane Surface Modification

A description of non-functional silane monomers and siloxane oligomers that are used to prepare hydrophobic and hydrophilic surfaces is presented in a 80 page brochure. The emphasis is on distinguishing the features and benefits of the entire range of commercial alkyl-silanes and aryl-silanes, including dipodal and fluorinated materials.



Reactive Silicones - Forging New Polymer Links

The 48 page brochure describes reactive silicones that can be formulated into coatings, membranes, cured rubbers and adhesives for mechanical, optical, electronic and ceramic applications. Information on reactions and cures of silicones as well as physical properties shortens product development time for chemists and engineers.



Silane Coupling Agents: Connecting Across Boundaries

Silane coupling agents enhance adhesion, increase mechanical properties of composites, improve dispersion of pigments and industrial minerals, provide crosslinking, immobilize catalysts and bind biomaterials. This 56 page brochure describes chemistry, techniques, applications and physical properties of silane coupling agents.



Silicon Compounds: Silanes and Silicones

Detailed chemical properties and reference articles for over 2,000 compounds. The 600 page catalog of silane and silicone chemistry includes scholarly reviews as well as detailed application information.



GELEST, INC.

provides focused technical solutions for specialty polymeric materials, textiles and surface modification applications that require bacteriostatic, fungistatic and algistatic properties.

Headquartered in Morrisville, PA *Gelest* is recognized worldwide as an innovator, manufacturer and supplier of commercial and research quantities of silanes, metal-organics and silicones, serving advanced technology markets through a material science driven approach.

For additional information on Gelest's Biosafe® Technology or to inquire on how we may assist in *Enabling Your Technology*, please contact:



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