



Enabling Your Technology

Safe and Persistent Antimicrobial Performance

Reprinted with permission from
SOFW Journal, August 2016



Safe and Persistent Antimicrobial Performance

D. J Wagner II*

abstract

While microorganisms are essential and symbiotic, bacteria, fungi and viruses can also cause disease. They can be removed mechanically, thermally, and as this article describes, chemically, with Gelest's BIOSAFE® antimicrobial, a condensed polymeric silane quaternary ammonium salt. Independent studies show that hand sanitizer formulas containing the BIOSAFE antimicrobial in conjunction with another quaternary ammonium compound meet and exceed U.S. Food & Drug Administration efficacy criteria for hand sanitizer antimicrobial protection.

Introduction

The world we know could not exist without microorganisms. Human beings have more microorganisms in their gut than cells in their entire body. Ten million microbes can inhabit a space no larger than the period at the end of this sentence. They are essential and symbiotic, but sometimes cause problems as well. Problems range from aesthetic issues like odor and staining to allergies, illness, and disease: bacteria, fungus, and viruses. They are everywhere, and they are adaptable and resourceful.

To reduce an unwanted microbial population for purposes of improving hygiene, or preventing odors and stains, one can control microorganisms by mechanical removal (water filtration), thermal removal (autoclave typical for medical instruments), and chemical removal (solutions for hard surfaces, textiles, and personal care). The focus of this article is chemical removal.

Antimicrobials provide chemical control of microbes. At the consumer level (i.e. not industrial or medical) antimicrobials fall into three general categories; static agents, sanitizers, and disinfectants. Microbiostatic agents are a proactive approach, and a long-term preventative measure to protect against microbial contamination. When a contamination already exists, disinfectants and sanitizers reduce microorganisms to a level that is not harmful to health. "Sanitizers" typically provide a reduction of the viable organism population by greater than 99.9% while "disinfectants", by comparison, should reduce 99.9–99.9999% of viable microorganisms.

Selection Factors and Chemistry

When selecting an active antimicrobial ingredient, some aspects to consider are:

- Target organism(s): bacteria, fungus, virus, and spores?
- Solubility: Is the formula alcohol based, or water based?

- Contact time: How quickly must the product perform for its intended use?
- Persistence: Does the product need to provide lasting protection?
- Toxicity: What is the sensitivity of the application regarding toxicity?
- Target surfaces: Will it be applied to hard surfaces, fabric or skin?
- Odor: Are active ingredients with strong odors acceptable?
- Cost: How price-sensitive is the application?

Common Types of active antimicrobial ingredients are:

- Acids
- Alkalies
- Alcohols
- Aldehydes
- Chlorine Active Compounds
- Iodophores
- Phenolic
- Peroxygen
- Quaternary Ammonium Compounds (QACs)

Gelest Inc., through its recent acquisition of BIOSAFE, Inc. is a manufacturer of a unique chemistry that provides long lasting microbiostatic activity and is synergistic with many formulas.

The active ingredient in BIOSAFE’s antimicrobial product is a condensed polymeric silane quaternary ammonium salt. This polymer has the novel combination of broad spectrum activity and ultra-low toxicity. The zero-VOC ingredient is available as a dry free-flowing powder or in water solutions up to a 5 % concentration.

Many antimicrobial products marketed to consumers contain quaternary ammonium compounds (QAC). The active moiety in BIOSAFE® antimicrobial is also a “quat”, so the two compounds are compatible and synergistic. A traditional QAC such as benzalkonium chloride provides immediate, short-term sanitization and disinfection (in the wet phase) and the BIOSAFE material, with its silicon base, anchors to surfaces, fabrics, and yes even skin, and provides long-term protection (dry surface). Some specialized solutions, synergistic mixtures, and proprietary formulated products are used by Gelest’s customers to incorporate BIOSAFE in home care formulations for cleaning floors, walls, and bathrooms (hard-surface cleaners) and detergents and softeners for washing machines, and most recently, alcohol-free hand sanitizer formulations.

Consumer Antiseptics

Hand sanitizers are considered “consumer antiseptics” by the U.S. Food and Drug Administration (FDA), and fall under the Tentative Final Monograph (TFM) for over-the-counter (OTC) Healthcare Antiseptic Drug Products, published in 1994. The TFM details which active ingredients can be used in hand sanitizer formulas, and at what concentrations those ingredients must be used to be safe and effective.

Tab. 1 shows the use patterns of active ingredients in consumer antiseptics. Notably “leave-on” hand products (hand sanitizers) use two main types of actives, alcohol and quats. When formulated with condensed polymeric silane quaternary ammonium salt like BIOSAFE, these hand sanitizers benefit from the extended protection that the persistent polymer provides.

Product Type	Active Ingredient					
	ALC	BKC “Quat”	BZC “Quat”	PCMX	TCC	TCS
Rinse-off handwash			•	•	•	•
Leave-on handwash	•	•	•			
Bodywash				•	•	•

ALC, alcohol; BKC, benzalkonium chloride; BZC, benzethonium chloride; PCMX, para-chloro-meta-xyleneol; TCC, triclocarban; TCS, triclosan.

Tab. 1 Use patterns of active ingredients

	Alcohol	Quat + BIOSAFE
Kills 99.9 % of all Germs and Bacteria	Yes	Yes
Odor Free	No	Yes
Non-Flammable	No	Yes
Non-Irritating	No	Yes
Residual and Persistent	No	Yes
Breaks through Dirt	No	Yes
Antiseptic (can be applied to wounds)	No	Yes
Moisturizing and Softening	No	Yes
Non-Poisonous	No	Yes

Tab. 2 Hand sanitizer characteristics

Why not Soap? The Benefits of Hand Sanitizers

Soap has been used for thousands of years and is very effective at cleaning one’s hands. In some cases, soap and water (preferably hot) are not available or convenient. And at times one needs to reduce the number of germs on the skin more than the mechanical action of plain soap, and/or needs a residual effect (i.e., persistent protection).

The World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) in the U.S. recommend persistent antiseptics for hand sanitizers. Persistence in this case is defined as extended antimicrobial activity that prevents or inhibits the growth of microorganisms after the product is used. This activity may be demonstrated by sampling the hands (or porcine for *in vitro*) several minutes or hours after use and showing residual antimicrobial effectiveness. Thus the term „residual activity.“

Hand Sanitizer Claims

The FDA TFM also lists the claims a consumer hand sanitizer can bear. Such claims are that a sanitizer: Prevents Overt Skin Infections; Controls Infection; can be used for Degerming; Kills Germs; Reduces the Risk of Infection and Cross-Contamination; and is a Microbiocidal; Bacteriostatic/Bactericidal; or First Aid Product.

Traditional hand sanitizers are 60 % ethyl alcohol. Drawbacks include flammability, irritation, and dry cracking hands for frequent users. By contrast, hand sanitizer formulas based on Quat+BIOSAFE are non-flammable, non-irritating and leave the hands feeling silky smooth because of the quaternary ammonium compound and the polymeric silicon-containing BIOSAFE. (Tab. 2)

Safety

The BIOSAFE condensed polymeric silane quaternary ammonium salt has undergone

the following safety studies and passed all with no untoward effects.

- 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 OPPTS 870.1100
- Acute Inhalation Toxicity Study OPPTS 870.130
- Skin Sensitization OPPTS 870.2600
- HRIPT Human Repeat Insult Patch Test
- AMES- Mutagenicity
- HETCAM- Eye irritation

Effectiveness

In a study of one such Quat+BIOSAFE formula, each of 12 human subjects was contaminated with pathogenic bacteria. They were then asked to pour a 60 % alcohol solution into the cupped hands and rub vigorously for a total of 60s onto the skin up to the wrists in accordance with the standard handrub procedure. They then rubbed their hands in a petri dish. The procedure was repeated exactly, using the BIOSAFE+QAC formula in place of the 60 % alcohol solution. The results were as good or better than the alcohol-based results, and demonstrate an average 5.31 log reduction vs an average 5.25 log reduction for the alcohol based hand sanitizer formula.

In the standard test procedure, the number of test organisms released from the fingertips of artificially contaminated hands is assessed before and after the hand sanitizer. The ratio of the two resulting values is called the reduction factor. It represents a measure of antimicrobial activity of the hand sanitizer tested. In this case a total of twelve (12) healthy adults were chosen, with each one carrying out the test procedure in precisely the same way.

In another study of a Quat+BIOSAFE hand sanitizer formula performed by a Gelest customer, samples of porcine skin (used as a human skin analog) were prepared and sanitized with 70 % ethanol. A test group was also treated with a hand sanitizer (Quat+BIOSAFE with Aloe Vera) and left at room temperature for up to 24 hours. At predetermined time intervals, an inoculum of *Staphylococcus aureus* was applied to the samples. After inoculation, samples were enumerated for *S. aureus*. Counts for the samples not treated with the sanitizer were compared to the treated samples to determine the effect of the sanitizer at preventing attachment of the organism.

The data in this study (Tab. 3) indicates that the hand sanitizer (Quat+BIOSAFE with Aloe Vera) was able to prevent the attachment of *Staphylococcus aureus* for some time periods. The calculated percent efficacy of the treatment peaked at 99.9 % (i.e. 3 logs of reduction) 2 minutes after application. Percent efficacy remained above 99.0 % (2 logs of reduction) for up to an hour after application and remained above 90.0 % (1 log of reduction) for up to 4 hours after application.

The FDA efficacy criteria for hand sanitizers requires that a product demonstrates at least a 2-log reduction within 5 minutes after the first use, and a 3-log reduction within 5 minutes after the tenth use. The Quat+BIOSAFE formulation

Holding Time (Sample Type)	Sample 1	Sample 2	Average	Log ₁₀	% Reduction
2 minutes (Untreated)	22,400,000	16,400,000	19,400,000	7.29	99.9
2 minutes (Treated)	11,200	13,900	12,550	4.10	
1 hour (Untreated)	5,200,000	18,800,000	12,000,000	7.08	99.0
1 hour (Treated)	87,000	164,000	125,500	5.10	
2 hours (Untreated)	13,900,000	15,900,000	14,900,000	7.17	98.3
2 hours (Treated)	137,000	380,000	258,500	5.41	
4 hours (Untreated)	8,200,000	17,200,000	12,700,000	7.10	96.9
4 hours (Treated)	156,000	640,000	398,000	5.60	
8 hours (Untreated)	9,500,000	13,700,000	11,600,000	7.06	84.9
8 hours (Treated)	1,580,000	1,930,000	1,755,000	6.24	
16 hours (Untreated)	3,700,000	14,900,000	9,300,000	6.97	79.5
16 hours (Treated)	1,770,000	2,040,000	1,905,000	6.28	
24 hours (Untreated)	10,500,000	15,400,000	12,950,000	7.11	54.1
24 hours (Treated)	3,400,000	8,500,000	5,950,000	6.77	
24 hours (Uninoculated)	<1	<1	<1	n/a	n/a

Tab. 3 *S. Aureus* reduction efficiency

exceeds this performance criteria and adds the benefit of durable persistent antimicrobial protection between cleanings.

Hand Hygiene

Keeping hands clean through improved hand hygiene is one of the most important steps one can take to avoid getting sick and spreading germs to others. Many diseases and conditions are spread by not washing hands. Using a hand sanitizer is not a substitute for washing hands and it is not recommended to wash hands less frequently or lower the best practices of hand washing and personal hygiene. CDC recommends you wash your hands or use a hand sanitizer in any of the following situations:

- Before, during, and after preparing food
- Before eating food
- Before and after caring for someone who is sick
- Before and after treating a cut or wound

- After using the toilet
- After changing diapers or cleaning up a child who has used the toilet
- After blowing your nose, coughing, or sneezing
- After touching an animal, animal feed, or animal waste
- After handling pet food or pet treats
- After touching garbage

Conclusion

If soap and water are unavailable, a Quat+BIOSAFE hand sanitizer can provide immediate removal of dangerous germs from your hands, and the persistent polymer (BIO-SAFE) can extend that protection for long periods of time.

contact

Donald J Wagner II
Technical Marketing Manager

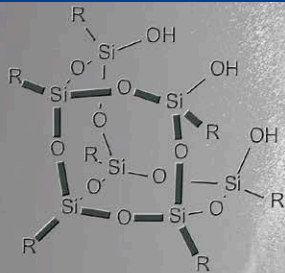
Gelest, Inc.
11 East Steel Rd.
Morrisville, PA 19067 | USA

Email: dwagner@biosafe.com



Enabling Your Technology

POLYMERS AND MICRO PARTICLES FOR PERSONAL CARE AND COSMETICS



APPLICATIONS

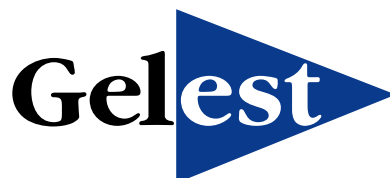
ALCOHOL-FREE HAND SANITIZERS
CLEANSERS AND CONDITIONERS
LOOSE POWDERS
PRESSED POWDERS
WATER-IN-SILICONE FOUNDATIONS
WATER-IN-OIL FOUNDATIONS

BENEFITS

ANTIMICROBIAL
LOW SURFACE ENERGY
WIDE VISCOSITY RANGE
SPREADING BEHAVIOR
LOWER REACTIVITY
BIOCOMPATIBILITY
UV-RESISTANCE
MODIFIED HYDROPHILIC- LIPOPHILIC BALANCE

www.GELEST.com

Phone (215) 547-1015



Enabling Your Technology

For more information, contact Gelest, Inc., 11 East Steel Rd., Morrisville, PA 19067

Phone: (215) 547-1015; Toll-Free: (888) 734-8344; Email: info@gelest.com

www.gelest.com