Section 18 Public Health Emergency Exemption

2020

SurfaceWise™ 2

1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride

EPA Reg. No. N/A

To reduce the spread of COVID-19 by controlling the SARS-CoV-2 virus on surfaces in two - Total Orthopedics Sports & Spine clinics in Texas

File Number: 20-TX-xx

Allied BioScience, Inc.

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Letter of Transmittal

TEXAS DEPARTMENT OF AGRICULTURE
COMMISSIONER SID MILLER

June 5, 2020

Ms. Tawanda Maignan,
Emergency Exemption Team Leader
Risk Integration, Minor Use, and Emergency Response Branch
U.S. EPA Office of Pesticide Programs
2777 Crystal Drive
Arlington, VA 22202
Maignan.Tawanda@epa.gov

Dear Ms. Maignan:

The Texas Department of Agriculture (TDA) hereby requests a Public Health Emergency Exemption under the provisions of Section 18 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, for the use of 3-(trihydroxysilyl)propyldimethyloctadecyl ammonium chloride (SurfaceWise™ 2, unregistered) to control SARS-CoV-2 on surfaces and to reduce the spread of COVID-19 for two - Total Orthopedics Sports and Spine facilities within the state of Texas.

The COVID-19 pandemic has created significant health and safety concerns for Total Orthopedics patients and staff. COVID-19 has harmed Total Orthopedics business and the national economy. It is critically important to Total Orthopedics to provide protection for their employees and patients against the SARS CoV-2 virus so that their medical services can begin to return to normal operations.

Total Orthopedics believes deploying SurfaceWise™ 2 as part of their cleaning regimen can provide continuous antimicrobial protection between their normal disinfecting protocols. Total Orthotics is convinced that SurfaceWise™ 2 will add a beneficial layer of protection to their facilities.

This is the first year TDA has requested a public health exemption for this product on this use site. Allied BioScience, Inc. has been notified of Total Orthopedics request for this Section 18, and supports its registration. Approval of SurfaceWise™ 2 for this use will provide Total Orthopedics patients and staff additional protection against the transmission of COVID-19 in Texas.

The requirements of 40 CFR 166.2o(a,d) along with supporting information are attached for your review. Thank you for your attention to this serious public health problem. If you have any comments or questions regarding this submission, please contact Mr. Kevin Haack at 512-463-6982 or email: Kevin.Haack@TexasAgriculture.gov .

Sincerely,

Mr. Philip Wright
Administrator for Regulatory Affairs
Texas Department of Agriculture

2

40 CFR Requirements

Section 18 Public Health Emergency Exemption

2020

SurfaceWise™ 2

1-Octadecanaminium,N,N-dimethyl-
N-[3-(trihydroxysilyl)propyl],chloride

EPA Reg. No. unregistered

To reduce the spread of COVID-19
by controlling the SARS-CoV-2 virus on surfaces
in two - Total Orthopedics Sports & Spine clinics in Texas

File Number: 20-TX-xx

Allied BioScience, Inc.

2020 FIFRA SECTION 18

General information requirements of §40 CFR 166.20(a) in an application for a specific exemption.

TYPE OF EXEMPTION BEING REQUESTED
SPECIFIC
QUARANTINE
✓ PUBLIC HEALTH

SECTION 166.20(a)(1): IDENTITY OF CONTACT PERSONS

i. This application to the Administrator of the Environmental Protection Agency (EPA) for a specific exemption to authorize the use of *1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride,* (SurfaceWise™ 2, EPA Reg. No. **unregistered**) to reduce the spread of COVID-19 by controlling the SARS-CoV- 2 virus on surfaces in two - Total Orthopedics Sports & Spine clinics in Texas.

ii. Any questions related to this request should be addressed to:

Kevin D. Haack
Coordinator for Pesticide Product Evaluation and Registration
Texas Department of Agriculture
P.O. Box 12847
Austin, TX 78711
Phone: (512) 463-6982
kevin.haack@TexasAgriculture.gov

iii. The following qualified experts are also available to answer questions:

Registrant Representative:

Maha El-Sayed PhD
Chief Science Officer
Allied BioScience Inc.
5000 Legacy Drive, Suite 350
Plano TX 75024
510-320-4888
melsayed@alliedbioscience.com

Technical/Scientific (Health) Aspects Expert:

Dr. Steven Morgan MD
Total Orthopedics Sports & Spine
11 25 Raintree Circle #100
Allen, TX 75013
Phone: 214-763-3970

Other Qualified Experts:

David Lewis
Allied BioScience Regulatory Consultant
Lewis and Harrison
2461 South Clark Street Suite 710
Arlington, VA 22202
Phone: 202-393-3903 x112
dlewis@lewisharrison.com

SECTION 166.20(a)(2): DESCRIPTION OF THE PESTICIDE REQUESTED

i. **Common Chemical Name (Active Ingredient):** *1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride*

CAS No.: 199111-50-7

Trade Name: SurfaceWise ™ 2 (8.38 lbs. per gallon)

EPA Reg. No.: Unregistered

Formulation: Active Ingredient 0.75% (0.063 lbs. ai. per gallon)

;

Manufacturer: Allied BioScience, Inc.

SECTION 166.20(a)(3): DESCRIPTION OF THE PROPOSED USE

i. Applicators

Total Orthopedics employees or designated applicators. After training on the proper use of electrostatic sprayers.

ii. Sites to be treated:

Product is for use in the following Total Orthopedics Sports & Spine facilities:

McKinney Medical Village
7300 Eldorado Parkway, Suite 165
McKinney, TX 75070
Intended coverage: 15,000 square feet

1125 Raintree Circle #100
Allen, TX 75013
Intended coverage: 15,000 square feet

Surfaces to be treated with SurfaceWise™ 2:
Surfaces include all interior hard and soft surfaces that are non-food contact, including tables, chairs, cushion seats, bed frames, counters, floors, carpets, walls, curtains, doors, restrooms, waiting rooms, checkout stations, and cashier stations.

iii. Method of Application:

Electrostatic sprayer application (requires training)

iv. Rate of Application: (in terms of a.i. and product):

Product is ready-to-use; no further dilution is necessary.

Using an Electrostatic sprayer set to apply 1.0 gallon of product per hour (or 1.0 oz of a.i. per hour). 3200 square feet of surface area can be treated per applicator per hour.

v. Maximum Number of Applications:

Up to 4 times per year (at approx. 90-day intervals)

vi. Total Amount of Pesticide to be used: (in terms of a.i. and product):

This Section 18 petition seeks to allow the use of up to 37.5 gallons of SurfaceWise 2 used as a surface disinfectant to treat up to 120,000 square feet of Hard and soft non-food contact surfaces (Two – 15,000 square foot facilities treated up to 4 times each) inside two Total Orthopedics Sports and Spine clinics in the state of Texas.

9.375 gallons of SurfaceWise™ 2, applied at a rate of 3200 square feet per gallon , will cover 30,000 square feet per application.

Maximum Total Usage:
Four – 9.375 gallon applications = 37.5 total gallons of SurfaceWise™ 2 or approx. **2.4 pounds a.i.** (0.063 pounds a.i. per gallon of SurfaceWise™ 2)

vii. Duration of the Proposed use:

All year

viii. Restrictions and Requirements:

- Precleaning of surfaces with an EPA-Registered Disinfecting Cleaner prior to product application.
- Product application via electrostatic sprayer. Training required on use of electrostatic sprayer application prior to use.
- Applicators should wear N-95 masks, protective eyeware (safety glasses), long sleeved shirts, and chemical resistant gloves.
- Allow surfaces to dry completely prior to re-entry (approximately 10 minutes)
- FOR INTERIOR USE ONLY

SECTION 166.20(a)(4): ALTERNATIVE METHODS OF CONTROL

Alternative Antimicrobial products:

List N Products:
https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

Pesticides approved by EPA for use against SARS-CoV-2 are all contact disinfectants with no residual antimicrobial activity. These products are effective at time of application; however, treated surfaces can quickly become re-infected with human contact. Therefore, while offering immediate disinfecting activity against SARS-CoV-2, the only way to maintain clean surfaces is by reapplication every few hours. It is difficult for Total Orthopedics to shut down or delay patient appointments, as frequently as would be required to depend solely on currently approved antimicrobial to disinfect hard surfaces and reduce the risk of spread of COVID-2019.

There are three categories of EPA registered antimicrobial products with proven residual activity: first, are those that are effective for only a short period of time (1-2 hours); second are paint products designed primarily for application to nursing facilities, non-critical care areas in hospitals, doctor's offices, etc. (Sherwin Williams, Sanitizer #1, EPA Reg. No. 64695-1); and thirdly, certain copper surfaces (Antimicrobial Copper Alloys – Group 1, EPA Reg. No. 82012-1). None of these products are viable for immediate use in Total Orthpedics facilities.

SurfaceWise™ 2 is applied via electrostatic sprayer to efficiently cover large surface areas. The electrostatic sprayer application helps ensure complete surface coverage, whereas current cleaning practices have been demonstrated to miss key areas. It can cover up to approximately 3,500 square feet per hour.

SurfaceWise™ 2 is highly compatible with multiple surface types and materials commonly found in public spaces.

"Continuously active antimicrobials represent the third great Infection Prevention advancement of our era, along with Hand Hygiene and the Disinfecting Wipe."
Dr. Charles Gerba, Ph.D

Alternative Cultural Practices:

Face Masks. The use of facemasks is crucial for health workers and other people who are taking care of someone infected with COVID-19 in close settings (at home or in a healthcare facility). CDC does not recommend that people who are well wear a facemask to protect themselves from respiratory illnesses, including COVID-19.

Social distancing: Creating ways to voluntarily increase distance between people in settings where people commonly come into close contact with one another. Specific priority settings include schools, workplaces, events, meetings, and other places where people gather. You could spread COVID-19 to others even if you do not feel sick.

Closures. Temporarily closing child-care centers, schools, places of worship, sporting events, concerts, festivals, conferences, and other settings where people gather.

Wash your Hands. Frequently/often wash your hands with soap and water (20-second minimum). If soap and water are not available, use an alcohol-based hand rub (*use a hand sanitizer that contains at least 60% alcohol*).

Routinely Clean. Clean frequently touched surfaces on a regular basis.

Don't Touch your Face. Avoid touching your eyes, nose, and mouth with unwashed hands.

Stay Updated. The state of COVID-19 evolves daily. Make informed decisions based on facts, not fear. To see the most up-to-date information and to monitor travel advisories, visit Texas EDEN, DSHS, and CDC websites:

https://www.cdc.gov/
https://dshs.texas.gov/
https://texashelp.tamu.edu/

Subscribe to email updates from the CDC Health Alert Network.
https://emergency.cdc.gov/han/

SECTION 166.20(a)(5): EFFICACY OF USE PROPOSED UNDER SECTION 18

SurfaceWise™ 2 has demonstrated continuous antimicrobial activity after simulated cleaning cycles representing over 90 days of infield use as obtained from previous field studies. Attached power point presentation "**Emergency Exemption - *SurfaceWise*™ 2**" has the details regarding the field study and results.

SurfaceWise™ 2 is applied via electrostatic sprayer to efficiently cover large surface areas. The electrostatic sprayer application helps ensure complete surface coverage, whereas current cleaning practices have been demonstrated to miss key areas. It can cover approximately 3,200 square feet per hour.

SurfaceWise™ 2 is highly compatible with multiple surface types and materials commonly found in public spaces.

See slides 7-10 and 15-22 of attached presentation "**Emergency Exemption – *SurfaceWise*™ 2**" as well as four attached studies:

1) Gerba et al - AJIC 2015 **- Long-term efficacy of a self-disinfecting coating in an intensive care unit.**

2) Ellingson et al - CID 2019 - **Impact of a Novel Antimicrobial Surface Coating on Health Care–Associated Infections and Environmental Bioburden at 2 Urban Hospitals**

3) Gerba Transit Whitepaper -**Long Term Reduction of Bacteria on Surfaces in Public Buses**

4) Gerba etal-medRxiv-2020- **A continuously active antimicrobial coating effective against Human Coronavirus 229E**

A copy of these documents can be found under EFFICACY DATA (Tab 6) of this Section 18 Submission.

SECTION 166.20(a)(6): EXPECTED RESIDUES FOR FOOD USES

N / A Not intended for on crop use.

SECTION 166.20(a)(7): DISCUSSION OF RISK INFORMATION

Human Health Risks (Information Provided by Allied BioScience, Inc., see Tab 8):

Toxicity of Trimethoxysilyl Quats

A brief overview of the toxicity of the trimethoxysilyl quats is presented below. Further information on the toxicity of this compound can be found in Appendix C in a risk characterization document dated February 2, 2000.

The Agency has reviewed all toxicity studies submitted for the trimethoxysilyl quats and has determined that the toxicological database is sufficient for reregistration. The toxicological database for trimethoxysilyl quats is currently comprised of unpublished studies submitted to the Agency; however, limited data are available for these compounds. The data matrix for trimethoxysilyl quats includes acute toxicity studies, a subchronic dermal toxicity study, one subchronic oral study in rats, one developmental toxicity study in rats, and six mutagenicity studies (four of which have been classified as being acceptable).

General Toxicity Observations

Upon reviewing the available toxicity information, the Agency has concluded that there are no endpoints of concern for repeated oral or dermal exposure to the trimethoxysilyl quats. This conclusion is based on low toxicity observed in acute, subchronic and developmental studies conducted with the trimethoxysilyl quat compounds. The risk from inhalation exposure has not been characterized and an additional study designed to assess inhalation toxicity over time may be needed. In addition, severe toxicity has been observed with regard to skin and eye irritation.

Carcinogenicity Classification

There are no concerns for carcinogenicity for the trimethoxysilyl quats based on the results of the mutagenicity studies and the lack of any systemic toxicity being observed in the toxicity data base; therefore, no carcinogenic analysis is required.

Environmental Risk:

This product is intended for interior use.

Because there are no anticipated pesticide releases, no ecological effects nor environmental risks are anticipated.

SECTION 166.20(a)(8): COORDINATION WITH OTHER AFFECTED STATE OR FEDERAL AGENCIES

The following state/federal agencies were notified of the Texas Department of Agriculture's (TDA's) actions to submit an application for a specific exemption to EPA

- Texas Commission on Environmental Quality (TCEQ), Air Quality Control
- Texas Commission on Environmental Quality (TCEQ), Water Quality
- Texas Parks and Wildlife Department
- U.S. Fish and Wildlife Department

See MISCELLANEOUS (Tab 8) for a copy of these letters.

SECTION 166.20(a)(9): ACKNOWLEDGEMENT BY THE REGISTRANT

Allied BioScience, Inc. Corporation has been notified of this agency's intent regarding this application (see attached letter of support).

Allied BioScience, Inc. Corporation also provided a copy of a label with the use directions for this Emergency Exemption use (although this use is dependent upon the approval of this section-18 by EPA).

SECTION 166.20(a)(10): DESCRIPTION OF PROPOSED ENFORCEMENT PROGRAM

The State Legislature has endowed TDA with the authority to regulate the distribution, storage, sale, use and disposal of pesticides in the state of Texas. In addition, the EPA/TDA grant enforcement agreement provides the Department with the authority to enforce the provisions of the FIFRA, as amended, within the state. Therefore, the Department is not lacking in authority to enforce the provisions of an EPA Pesticide Enforcement Specialist will make a number of random, unannounced calls on applicators to check for compliance with provisions of the specific exemption. If violations are discovered appropriate enforcement will be taken.

SECTION 166.20(a)(11): REPEAT USES

This is the First time TDA has applied for this Public Health Exemption.

SECTION 166.25(b)(2)(ii): PROGRESS TOWARDS REGISTRAION

Acute GLP 6 pack completed

Micro data in progress

Chemistry data in progress

SECTION 166.20(d)(1): NAME OF THE PEST

Pest common name: Coronavirus, Human Coronavirus, Novel Coronavirus

Pest scientific name: SARS-CoV-2

Disease Transmitted: COVID-19

SECTION 166.20(d)(2): VECTORED DISEASE TRANSMISSION AND MAGNITUDE OF HEALTH PROBLEMS

Person-to-person spread. The virus is thought to spread mainly from person-to-person.

- Between people who are in close contact with one another (within about 6 feet).
- Through respiratory droplets produced when an infected person coughs, sneezes or talks.
- These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs.
- Some recent studies have suggested that COVID-19 may be spread by people who are not showing symptoms.

Contaminated Surfaces. It may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or possibly their eyes. This is not thought to be the main way the virus spreads, but we are still learning more about this virus.

May 3, 2020
— There are now more than 3.5 million cases of COVID-19 worldwide and more than 247,900 deaths, according to the Johns Hopkins dashboard. The U.S. has more than five times the number of cases than Spain, the second-highest in case count. More than 67,600 people have died in the U.S and the case count is still increases, according to CNN.

SECTION 166.20(d)(3): Treatment for the Health Problem

***Comprehensive Infection Control Guidance for Healthcare Professionals about Coronavirus (COVID-19):**

https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html

Availability of medical treatment to remedy any resultant health problem associated with the spread of the pest:

There is no vaccine to prevent COVID-19
There is medicine to treat COVID-19

Healthcare providers and those that fall ill can focus on treating the symptoms:

- Get plenty of rest.
- Drink fluids to prevent dehydration.
- Take medicine to reduce fever and pain.
- If taking medicine for another medical condition, one should discuss with their healthcare provider before taking additional medication.

You can find the latest public health information from CDC at www.coronavirus.gov and the latest research information from NIH at www.nih.gov/coronavirus.

3

Proposed Label

Allied BioScience

SurfaceWise2®

For Control of Coronavirus and to reduce the spread of COVID-19 in Total Orthopedics Sports & Spine Clinics in Allen, Texas & McKinney, Texas

FIFRA §18 Public Health Exemption
EPA File Number: 20TX__

Active Ingredient:
1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride … 0.75%
Other Ingredients..... 99.25%
Total… 100.00%

For Sale, Distribution, and Use only in the State of Texas

Effective Period: This FIFRA §18 Public Health Exemption becomes effective xx/xx/2020 and expires on xx/xx/2021.

Keep out of Reach of Children
Caution

FIRST AID	
If Inhaled	• Move person to fresh air. • If person in not breathing, call 911 or ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a Poison Control Center or doctor for treatment advice.
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a Poison Control Center or doctor for treatment advice.
If on Skin:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a Poison Control Center or doctor for treatment advice.
If Swallowed	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person.
Have the product container or label with you when calling a Poison Control Center, or doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center (1-800-222-1222).	

Net Contents:

PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using the toilet. Remove contaminated clothing and wash before reuse.

FOR INTERIOR USE ONLY.

Environmental hazards statement for end-use products in containers less than 5 gallons (liquid) or less than 50 pounds (solid, dry weight)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms.

Environmental hazards statement for end-use products in containers greater than or equal to 5 gallons (liquid) or greater than or equal to 50 pounds (solid, dry weight)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, ponds, streams, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Directions for Use: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read entire Directions for Use and Disclaimer of Warranties on this label and the product container before using this product. Follow all applicable directions, restrictions, Protective Equipment requirements, and other precautions.
This labeling must be in possession of the user at the time of pesticide application.
Any adverse effects resulting from the use of ***SurfaceWise 2®*** under this §18 specific exemption must immediately be reported to the Texas Department of Agriculture and the manufacturer.
Authorized Users: For sale only to ***Total Orthopedics Sports & Spine***. Only for use or application by users trained and authorized by Allied BioScience, Total Orthopedics Sports & Spine, or by users under their direct supervision. Users must be trained in the application of ***SurfaceWise2®*** by electrostatic sprayer or equivalent prior to use.
Product Application: Product is for use in the following Total Orthopedics Sports & Spine facilities:

McKinney Medical Village
7300 Eldorado Parkway, Suite 165
McKinney, TX 75070

Allen Location
1125 Raintree Circle #100
Allen, TX 75013

Total Coverage: Up to 37.5 gallons of SurfaceWise 2 used as a surface disinfectant to treat up to 120,000 square feet of Hard and soft non-food contact surfaces (Two – 15,000 square foot facilities treated up to 4 times each) inside two Total Orthopedics Sports and Spine clinics in the state of Texas. 9.375 gallons of SurfaceWise™ 2, applied at a rate of 3200 square feet per gallon, will cover 30,000 square feet per application (includes 2 – 15,000 square foot facilities).

Maximum Total Usage: Four – 9.375 gallon applications = 37.5 total gallons of SurfaceWise™ 2 or approx. 2.4 pounds a.i. (0.063 pounds a.i. per gallon of SurfaceWise™ 2)

Product is intended to help provide residual control of coronaviruses, including SARS-CoV-2, for up to 90-days on treated surfaces. Prior to application of ***SurfaceWise2®,*** the surface must be pre-cleaned/disinfected using an EPA registered disinfecting cleaner listed under List N: Disinfectants for use against SARS-CoV-2, https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2. Follow all applicable label use instructions. **DO NOT DILUTE *SurfaceWise 2*®.** Apply ***SurfaceWise 2®*** immediately following pre-cleaning & disinfecting by approved List N disinfectant/cleaners. ***SurfaceWise 2®*** should be applied by electrostatic sprayer, setting the flowrate to 1 gallon of product/hour. Application at this rate will cover approximately 3,200 ft^2/hr. Spray surfaces from a distance of 24-36 inches to the point of saturation being careful not to let the liquid start to drip. Be sure to apply to all surfaces paying particular attention to the underside of surfaces. A sheen will be present on the surface following treatment. Following application, allow treated surfaces to completely air-dry (approximately 10 minutes) prior to handling. Aircraft and airline facilities may be reentered following drying. Reapply coating at least once every 90-days. The average coating density should be maintained at a minimum of 0.3mg/in^2 as determined by abrasion testing or other agreed to means.
Personal Protective Equipment: Applicators must wear long sleeved shirts, chemical resistant gloves, and NIOSH approved N-95 or KN-95 respirators.

Storage and Disposal: Do not contaminate water, food, or feed by storage of disposal.
Pesticide Disposal: Any unused/unopened containers of ***SurfaceWise 2®*** must be either returned to the manufacturer or disposed of in accordance with applicable RCRA regulations following the expiration of the emergency exemption.
Container Disposal: Do not reuse or refill this container. **If empty**, place in trash or offer for recycling if available. **If partly filled,** contact your local solid waste disposal agency for disposal instructions. Never place unused product down any indoor or outdoor drain. Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

NOTICE OF WARRANTY AND LIMITATION OF LIABILITY
Allied BioScience, Inc. warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with directions for use under normal use conditions. It is impossible to eliminate all risks inherently associated with use of this product. Ineffectiveness or other unintended consequences may result because of such factors as the presence of other materials, or the manner of use or application, all of which are beyond the control of Allied BioSciences. In no case shall Allied BioScience be liable for consequential, incidental, special, punitive, direct or indirect damages or any other loss resulting from the use or handling of this product. All such risks shall be assumed by the Buyer Buyer's remedy for any claim of breach of this warranty is expressly limited to return of this product and repayment of the purchase price. Allied BioScience MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

Manufactured by:
Allied BioScience, Inc.
5000 Legacy Drive, Suite 350
Plano, Texas 75024

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes and clothing. Avoid breathing vapors or spray mist. Wear protective eyewear (safety glasses), long sleeves, and chemical resistant gloves while handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using the toilet. Remove contaminated clothing and wash before reuse.

FOR INTERIOR USE ONLY

ENVIRONMENTAL HAZARDS:

This pesticide is toxic to fish and aquatic organisms.

FIRST AID:

If Inhaled: Move person to fresh air. If person in not breathing, call 911 or ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a Poison Control Center or doctor for treatment advice.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice.

If on Skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.

If Swallowed: Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

Have the product container or label with you when calling a Poison Control Center, or doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center (1-800-222-1222).

MANUFACTURED BY:
Allied BioScience, Inc.,
100 Crescent Court, Suite #450
Dallas, TX 75201

Allied BioScience

SurfaceWise 2

Active Ingredient:

1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride.....0.75%
Other Ingredients.....99.25%
TOTAL.....100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

1 GALLON

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store away from food and pet food. Keep container closed when not in use. Do not transfer contents to other containers. Protect pesticide containers from extreme heat and cold.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain. Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

DIRECTIONS FOR USE

Clean surface prior to application.

HOW TO APPLY

Using an electrostatic sprayer, spray surfaces from a distance of about 36 inches to the point of saturation, being careful not to let the liquid start to drip. A sheen will be present on the surface when complete.

Once applications are complete, allow the treated surfaces to dry completely (approximately 10 minutes).

SURFACE CARE AND REAPPLICATION SCHEDULE

Reapply according to manufacturer's directions.

8 60002 52475 7

LOT # _____

ALLIED BIOSCIENCE, INC.
SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

Product Identity: **SURFACEWISE 2**

Recommended use: Surface treatment
Restrictions on Use: None known.

Supplier: Allied BioScience, Inc.
100 Crescent Ct. STE 450
Dallas, TX 75201-7822
1-888-224-5057

Emergency Phone: 1-888-224-5057 (M-F 9AM-5PM Central Time)

2. HAZARDS IDENTIFICATION

GHS Classification:

Physical:	Health:	Environmental
Not classified as hazardous	Not classified as hazardous	Not classified as hazardous

GHS Label Elements: Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No.	Amount
1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride	199111-50-7	0.75%
Other Ingredients	Mixture	Balance

The exact percentage is a trade secret.

4. FIRST AID MEASURES

Eye: Flush victim's eyes with water for several minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin: Wash skin with soap and water. Get medical attention if irritation persists.
Ingestion: Do not induce vomiting. Get medical attention.
Inhalation: Move victim to fresh air. Get medical attention if symptoms develop or irritation persists.

Most important Symptoms: May cause temporary eye irritation. Prolonged or repeated skin contact may cause mild irritation. Swallowing may cause gastrointestinal irritation.

Indication of immediate medical attention/special treatment: Immediate medical attention is not generally required,

5. FIRE FIGHTING MEASURES

Suitable (and Unsuitable) Extinguishing Media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Not flammable or combustible. Thermal decomposition may produce oxides of carbon, silicon and nitrogen and chlorine compounds.
Special Protective Equipment and Precautions for Fire-Fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water spray. Do not allow run-off from firefighting to enter drains or water courses.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures: Evacuate spill area and keep unprotected personnel away. Avoid breathing mists. Avoid contact with the eyes. Avoid prolonged contact with skin and clothing. Wear appropriate protective clothing.

Methods and Materials for Containment and Cleaning Up: Contain and collect using inert absorbent materials and place in appropriate containers for disposal. Do not flush to sewer. Report releases as required by local, state and federal authorities.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Avoid contact with eyes, skin and clothing. Avoid breathing mists. Wear appropriate protective clothing and equipment. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Conditions for Safe Storage, Including Any Incompatibilities: Do not contaminate water, food or feed by storage or disposal. Store in original container.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines:

1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride	None Established

Engineering Controls: Use with adequate general or local exhaust ventilation to minimize exposure levels.

Personal Protective Equipment: Refer to the product label for additional requirements for pesticide use.

Respiratory Protection: In operations where exposure levels are excessive, an approved respirator with dust/mist cartridges or supplied air respirator can be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.
Skin Protection: Wear impervious gloves if needed to avoid prolonged or repeated skin contact.
Eye Protection: Chemical safety goggles should be worn if splashing is possible.
Other: Impervious clothing recommended where needed to avoid skin contact and contamination of personal clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Clear, colorless liquid. Amine-like odor

Physical State: Liquid	**Odor Threshold:** Not Determined
Vapor Density: Same as water	**Initial Boiling Point/Range:** Not Determined
Solubility in Water: Soluble	**Vapor Pressure:** Same as water
Relative Density: 1.005	**Evaporation Rate:** Same as water
Melting/Freezing Point: Not Determined	**pH:** 11

VOC Content: Not Determined	**Octanol/Water Coefficient:** Not Determined
Viscosity: Not determined	**Decomposition Temperature:** Not determined
Flashpoint: None	**Flammability (solid, gas):** Not applicable
Flammable Limits: LEL: Not applicable **UEL:** Not applicable	**Autoignition Temperature:** Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not normally reactive
Chemical Stability: Stable under normal storage and handling conditions.
Possibility of Hazardous Reactions: None known.
Conditions to Avoid: None known.
Incompatible Materials: None known.
Hazardous Decomposition Products: Thermal decomposition yields oxides of nitrogen, carbon and silicon and chlorine compounds.

11. TOXICOLOGICAL INFORMATION

HEALTH HAZARDS: The following information is based on studies with similar materials.

Eye: Contact may mild, temporary irritation with redness, tearing and stinging. Rabbit studies with similar materials did not meet the criteria for classification.
Skin: May cause mild skin irritation. Similar materials were non-irritating in rabbit studies.
Ingestion: Swallowing may cause mild irritation to the mouth and intestinal tract.
Inhalation: Inhalation of mists may cause mild mucous membrane and respiratory irritation.
Chronic: None known.
Sensitization: Similar products were negative in the LLNA.
Carcinogenicity: None of the components are listed as a carcinogen or suspected carcinogen by IARC, NTP, ACGIH, OSHA or the EU CLP.
Germ Cell Mutagenicity: Components are not germ cell mutagens.
Reproductive Toxicity: Components are not reproductive toxins.

Numerical Measures of Acute Toxicity:
Oral rat LD_{50} >5000 mg/kg, EPA category 4
Dermal rat LD_{50} >5050 mg/L, EPA category 4
Inhalation rat LC_{50} >5.04 mg/L/4 hr (as mist – no mortality), EPA category 4
Eye irritation: Practically non-irritating, EPA category 4
Dermal irritation rabbit: Non-irritating, EPA category 4

12. ECOLOGICAL INFORMATION

Dermal sensitization mice: Not have skin sensitization effect

Ecotoxicity: No data is available for the product. Components may be harmful to aquatic organisms. Releases to the environment should be avoided.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No data available.
Mobility in Soil: No data available.
Other Adverse Effects: No data available.

13. DISPOSAL CONSIDERATIONS

Waste resulting from the use of this product may be disposed of on site. Deactivation of the product may be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of the product. Dispose in accordance with all state, local and federal regulations.

14. TRANSPORT INFORMATION

DOT Hazardous Materials Regulations: Not regulated

15. REGULATORY INFORMATION

CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Hazard Category for Section 311/312: Refer to Section 2 for the OSHA Hazard Classification.

Section 313 Toxic Chemicals: This product contains the following chemicals subject to SARA Title III Section 313 Reporting requirements: None

Section 302 Extremely Hazardous Substances (TPQ): None

California Proposition 65: This product is not known to contain regulated chemicals.

16. OTHER INFORMATION

SDS Date of Preparation: May 27, 2020

NOTICE

Allied BioScience, Inc. (ABS) provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. A properly trained person using this product intends this document only as a guide to the appropriate precautionary handling of the material. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. ABS makes no representations or warranties, either expressed or implied, including without limitation any warranties of merchantability, fitness for a particular purpose with respect to the information set forth herein or the product to which the information refers. Accordingly ABS will not be responsible for damages resulting from use of or reliance upon this information.

Pages 27-34 *Inert ingredient information may be entitled to confidential treatment*

4

Map of Texas - Showing Requested Use Sites

Section 18 Public Health Emergency Exemption

To reduce the spread of COVID-19
by controlling the SARS-CoV-2 virus on surfaces
in two - Total Orthopedics Sports & Spine clinics in Texas

Sites to be treated:

McKinney Medical Village
7300 Eldorado Parkway, Suite 165
McKinney, TX 75070
Intended coverage: 15,000 square feet

1125 Raintree Circle #100
Allen, TX 75013
Intended coverage: 15,000 square feet

5

Letters of Support and Registration Status

The Total Orthopedics Sports and Spine Requests for an Emergency Public Health waiver for the use of SurfaceWise 2

To Whom It May Concern

I am Dr Steven B. Morgan MD. I am requesting that the Texas Agriculture Department (TDA) review and submit on t heir behalf a FIFRA Section 18 Emergency Exemption Request for the use of the product called SurfaceWise™ 2 in its all our Clinic locations to help protect their surfaces against Coronavirus and reduce the risk of COVID 19 t ransmission .

The COVID pandemic has resulted in economic hardship and reduced access to services across the united states. As we open up our country and our economy again, my offices and clinics wants to make sure we are doing everything we can to create as safe experience for our patients and staff. In addition to our regular and planned disinfecting protocols, we would like to add the protection of a continuous antimicrobial to help control pathogen contamination in between these disinfecting protocols. There are no EPA registered pesticides capable of providing the type of continuous antimicrobial protection that Surface Wise™ 2 can provide. I have reviewed the supporting information for SurfaceWise 2 and am convinced it will add a beneficial layer of protection to our facilities.

The anticipated product coverage will include:

Dr Office and Physical Therapy in Allen Texas (15,000 square feet of coated surfaces)

Dr. Office in McKinney Texas (15,000 square feet of coated surfaces)

Steven B. M org a M.D.
214-763-3970

1125 Raintree Circle #100
Allen , TX 75013

From: Victor Mendoza <vmendoza@blackridgetx.com>
Sent: Tuesday, April 7, 2020 3:15 PM
To: Tim Kleinschmidt <Tim.Kleinschmidt@TexasAgriculture.gov>
Cc: Rusty Kelley <rkelley@blackridgetx.com>
Subject: Section 18 Pesticide Exemption

WARNING: This email originated from outside of the Texas Department of Agriculture email system. DO NOT click links or open attachments unless you expect them from the sender and know the content is safe.

Tim, thanks for taking our call this afternoon. I've attached a number of docs Dale and his team may wish to review.

Background

- The product is called "*SurfaceWise*™ 2" and was developed by Allied BioScience, Inc.
- Application is via electrostatic spray @ 0.5 gallon/hr (active ingredient @ 0.5 oz/hour)
- Brief explanation re: exemption request—
    - Pesticides approved by EPA for use against SARS-CoV-2 are all contact disinfectants with no residual antimicrobial activity.
        - These products are effective at time of application; however, treated surfaces can quickly become re-infected with human contact.
        - Therefore, while offering immediate disinfecting activity against SARS-CoV-2, the only way to maintain clean surfaces is by reapplication every few hours.
    - *SurfaceWise*™ 2 has demonstrated continuous antimicrobial activity after simulated cleaning cycles representing over 90 days of infield use as obtained from previous field studies.
    - *SurfaceWise*™ 2 is highly compatible with multiple surface types and materials commonly found in public spaces.
        - In addition, the electrostatic sprayer application helps ensure complete surface coverage, whereas current cleaning practices have been demonstrated to miss key areas.
            - It can cover approximately 3,500 square feet per hour.

Attachments

1) Photo Image of *SurfaceWise*™ 2 Label, Gallon Jug
2) PDF of *SurfaceWise*™ 2 SDS
3) PDF Overview Slideshow Presentation

Please let me know if I can help, in any way, or provide additional information for Dale's initial assessment.

Thanks again.

-Vic

6 Efficacy Data

<u>Study 1</u>

Gerba et al - AJIC 2015 –

Long-term efficacy of a self-disinfecting coating in an intensive care unit.

American Journal of Infection Control 42 (2014) 1178-81

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major article

Long-term efficacy of a self-disinfecting coating in an intensive care unit

Akrum H. Tamimi PhD, Sheri Carlino BS, Charles P. Gerba PhD *

Department of Soil, Water, and Environmental Science, University of Arizona, Tucson, AZ

Key Words:
Disinfection
Bacteria
Self-disinfecting surface
Efficacy

Background: Cleaning and disinfecting fomites can effectively remove/kill pathogens on surfaces, but studies have shown that more than one-half the time, surfaces are not adequately cleaned or are recontaminated within minutes. This study evaluated a product designed to create a long-lasting surface coating that provides continuous disinfecting action.

Methods: This study was performed in an intensive care unit (ICU) in a major hospital. Various sites within the ICU were cultured before treatment and then at 1, 2, 4, 8, and 15 weeks after application of an antimicrobial coating. Samples were cultured for total bacteria, as well as *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant enterococcus, and carbapenemase-resistant Enterobacteriaceae.

Results: The average bacterial count on all treated surfaces was reduced by >99% (2 logs) for at least 8 weeks after treatment. Overall, average levels of bacteria never returned to those observed before treatment even after 15 weeks. Antibiotic-resistant bacteria were found on 25% of the sites tested before treatment, but were isolated at only 1 site during the 15 weeks after treatment.

Conclusions: The product assessed in this study was found to have persisted over 15 weeks in reducing the total number of bacteria and antibiotic resistant bacteria on surfaces within an ICU.

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Contamination of inanimate objects (fomites) and surfaces are known to contribute to the transmission of health care-associated infections (HAIs), especially those related to antibiotic-resistant bacteria.[1] Some infection control guidelines recommend the routine disinfection of patient care surfaces, especially high-touch objects. Such objects presumably contribute to the transmission of pathogens by contaminating the hands of health care workers who subsequently contact patients.[1,2]

Routine and terminal cleaning of surfaces using hospital-grade disinfectants is an accepted method for controlling the spread of infectious agents. Cleaning and disinfecting fomites can effectively remove/kill pathogens on surfaces, but studies have shown that more than one-half the time, surfaces are not adequately cleaned and may be recontaminated within minutes.[2,3]

Commonly used disinfectants (eg, chlorine, hydrogen peroxide, quaternary ammonium compounds) provide no persistent residual activity after their application to disinfect surfaces, because they are easily washed away. In addition, application of disinfectants needs to be closely monitored, because cleaning cloths may reduce the effective concentration during actual use by cleaning crews.[4] Self-disinfecting surfaces that act against microbes on a continuing basis would specifically address these limitations in current cleaning and disinfecting practices.[5] Recently, copper surfaces have been shown to reduce the rate of occurrence of methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococcus (VRE) colonization of patients in ICU rooms, as well as the numbers of the organisms on surfaces.[6,7] They also have been shown to continuously reduce the concentration of total bacteria on bed rails within intensive care unit (ICU) rooms.[8]

The present study was designed to assess the effectiveness of ABS-G2015 (Allied BioScience, Point Roberts, WA), a formulation of a quaternary ammonium organosilane compound that binds to surfaces and produces a residual (ie, long-term) disinfecting activity. Our initial laboratory work demonstrated ABS-G2015's effectiveness against a wide range of pathogenic bacteria (eg, MRSA, *Pseudomonas aeruginosa*) and viruses (eg, MS-2 virus). The goal of this study was to assess its efficacy in a practical application in a health care environment.

* Address correspondence to Charles P. Gerba, PhD, Department of Soil, Water, and Environmental Science, University of Arizona, Tucson, AZ 85721.

E-mail address: gerba@ag.arizona.edu (C.P. Gerba).

This project was supported by Allied BioScience through funding supplied to the University of Arizona.

Conflict of interest: None to report.

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http://dx.doi.org/10.1016/j.ajic.2014.07.005

Table 1
Culture methods used for microbial isolation and identification

Organism	Culture method	Incubation conditions	Further analysis	Reference
Total bacteria	Spread plating on R2A medium (BD Diagnostics, Sparks, MD)	24^0 C for 5 d		13
C difficile	Incubation for 7 days in 0.1% sodium taurocholate and cycloserine-cefoxin fructose broth	Anaerobic conditions at 37^0 C for up to 5 d	A 2-mL aliquot was mixed with equal amounts of absolute ethanol. Bacteria were concentrated by centrifugation and pellets were used to inoculate cycloserine-cefoxtin fructose agar.	14
MRSA	Trypticase soy agar amended with 5% sheep's blood, 10 mg/L colistin, and 25 mg/naladixic acid using spread plate method	35^0 C for 24-48 h	b-hemolytic colonies were isolated and subcultured on trypticase case soy agar with no amendments and incubated at 35^0 C for 24-48 h.	15
CRE	Modified Hodge test; Muller-Hinton agar	35^0 C for 24 h		16
VRE	Bile esculin azide agar	37^0 C in CO_2 incubator for 24-48 h	Gram stain, catalase test	17

NOTE. From an original volume of 4 mL of sponge stick eluate. A 0.1-mL volume of this eluate was used for each assay.

Table 2
Average (arithmetic mean) total bacterial numbers (cfu) isolated on 100 cm^2 from fomites and percent reduction after treatment

		Weeks after treatment				
Variable	Baseline*	1	2	4	8	15
Number of samples	95	81	64	64	64	45
Average number of bacteria	233,064	98	80	43	2,247	3,320
Range	10-7,000,000	10-2,500	10-840	10-2,500	10-44,000	10-57,000
% reduction	NA	99.96	99.97	99.98	99.04	98.58

NA, not applicable.
*Before treatment.

Table 3
Percent cfu of total bacteria per 100 cm^2 exceeding values indicated

		Weeks after treatment				
Count, cfu per 100 cm^2	Baseline*	1	2	4	8	15
>100	71.5	11.1	17.2	12.8	51.2	33.3
>1,000	51.5	2.4	1.5	0	17.1	24.4
>10,000	25.2	0	0	0	4.6	11.1

*Before treatment.

MATERIALS AND METHODS

This study was conducted in a 24-bed ICU of a community hospital in Los Angeles County, California, between May 10 and September 30, 2013. Initial microbial sampling of various fomites was conducted to assess the levels of bacteria on various hospital surfaces before selection of study sites. After review, 95 sites in the ICU were selected for study.

In each patient room of the ICU, cultures were collected from the following sites: bed rails, bed controls, tray table, and wall above the sink. Samples also were collected from the 2 ICU nursing stations and waiting lobby, including countertops, phones, computer keyboards, chair armrests, and end tables. All movable items were inconspicuously tagged and coded over the course of the study so that the same objects (ie, surfaces) could be sampled.

Each of the sites was cultured before application of the ABS-G2015 product and at 1 week (6-8 days), 2 weeks (13-17 days), 4 weeks (29-32 days), 8 weeks (59-62 days), 15 weeks (104- 107 days) after application. Some objects were removed and were not available for culture at some of the subsequent time points. The ABS-G2015 coating comprises both quaternary ammonium silyl oxide and titanyl oxide moieties, and is not commercially available at present.

The ABS-G2015 coating was applied with an electrostatic spray applicator on all surfaces in the ICU, including hard surfaces (eg, beds, tray tables, bed rail, walls.) and soft surfaces (eg, drapes, cloth- and vinyl-covered chairs), and left wet to dry. Surface preparation and application were done by trained certified tech- nicians following a structured protocol. All applications were monitored for quality control by a manufacturer's representative. During the course of the study, hospital staff maintained their normal daily cleaning schedule, which involved disinfecting with reusable cloths containing bleach and/or reusable disposable quaternary ammonium wipes (PDI Sani-cloth; Professional Dis- posables International, Orangeburg, NY) containing dimethyl eth- ylbenzyl ammonium chloride and dimethyl benzyl ammonium chloride as active ingredients. No clinical interventions (eg, changes in hand hygiene practices) were instituted during the study period.

Microbial methods

Areas of 100 cm^2 were sampled using a sponge stick containing Letheen broth (3M, St Paul, MN) to neutralize any residual disinfectant. After collection, the samples were immediately placed on ice packs and sent overnight to the University of Arizona. On receipt, the broth was extracted from the sponge stick by manual agitation, and 4 mL of extracted broth was assayed using selective media for isolation of the various bacteria. Samples were cultured for total bacteria, *Clostridium difficile*, MRSA, VRE, and carbapenemase-resistant *Enterobacteriaceae* (CRE). Test methods for each organism are presented in Table 1. Total bacteria were measured using R2A medium and 5 days of incubation, which have been found to be sensitive for detecting bacteria in environmental samples.[9,10]

Data analyses

The data on bacterial concentrations did not demonstrate a normal distribution. Even after log transformation, the data did not meet the conditions of normality and homogeneity. Thus, we used bootstrapping techniques to conduct analysis of variance for each stage between the baseline concentrations of the sampled fomites and the intervention concentrations of the same fomites to determine statistical significance differences, based on a rejection region of 5%.[11,12]

RESULTS

The average numbers of total bacteria detected per 100 cm^2 at all locations and percent reductions in total bacterial numbers after

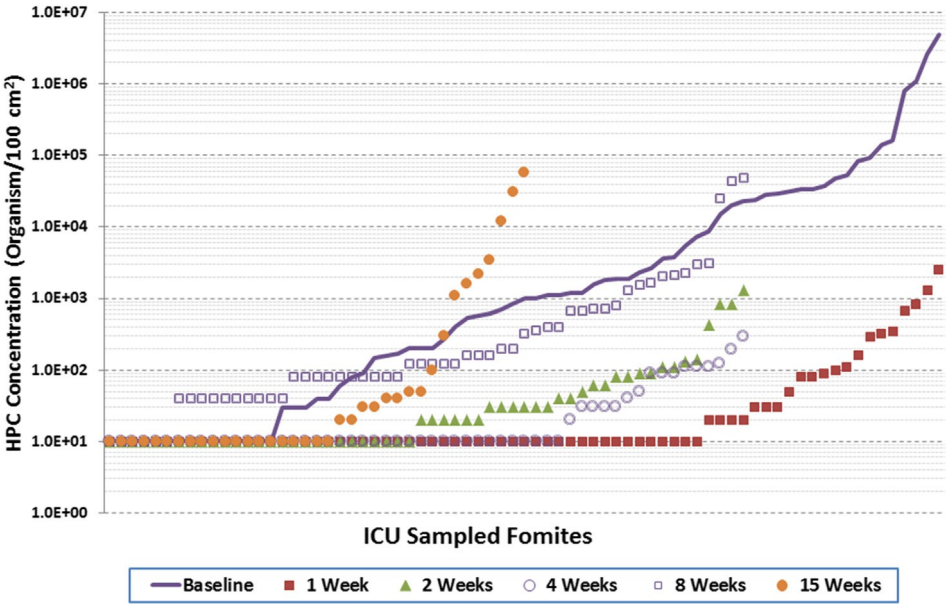

Fig 1. Total bacterial concentrations on sampled sites before and after treatment. Each dot represents the value at an individual sample site, from lowest value to highest value.

treatment are presented in Table 2. As shown in the table, bacterial numbers were always 99.9% (3 logs) less at 4 weeks after the treatment, 99% (2 logs) after 8 weeks, and still almost 99% (2 logs) after 15 weeks. Moreover, significantly, the number of sites containing >10,000 colony-forming units (cfu)/100 cm² was reduced from 71.5% of the sites before treatment to 0 for the next 8 weeks, and after even 15 weeks, only 11.1% of the sites exceeded this level (Table 3).

Bootstrapping analysis of variance was conducted for each stage between the baseline concentrations for the sampled fomites and the intervention concentrations for the same fomites to determine statistical significant differences based on a rejection region of 5%. Based on the *P* values (<.0005), there was a statistical significance difference between the baseline concentrations and the fomite concentrations during the entire 15 weeks of the study.

Colony counts of total bacteria per 100 cm² surface area for baseline samples (before treatment) and those collected after the application of the ABS-G2015 for fomites sampled in the ICU are represented graphically in Figure 1. This figure represents the distribution of bacterial numbers detected at each site before and after the intervention. Of note, peak values 15 weeks after treatment were still 100-fold (2 logs) less than those measured before treat- ment (baseline).

The percentage of samples in which antibiotic resistant bacteria were isolated at the various sites sampled is shown in Table 4. Antibiotic-resistant bacteria (except *C difficile*) were isolated from all study areas during the baseline sampling. VRE was the most commonly isolated organism. Before treatment, antibiotic-resistant bacteria were isolated from 25% of the sites (surfaces) sampled. After treatment, no antibiotic-resistant bacteria were isolated until week 8, when VRE was found in 1 of 64 samples (1.5%; from a chair armrest).

DISCUSSION

Fomites and surfaces in the health care environment are known to play roles in the transmission of pathogens.[1] This knowledge has led to the study and development of self-sanitizing surfaces as a means to improve on usual cleaning and disinfecting practices.[5]

Table 4
Isolation of antibiotic-resistant bacteria (percent of positive sites)

		Weeks after treatment				
Variable	Baseline*	1	2	4	8	15
Number of samples	95	81	64	64	64	45
VRE	14	0	0	0	1	0
MRSA	7	0	0	0	0	0
CRE	3	0	0	0	0	0
C difficile	0	0	0	0	0	0
Overall percentage	25	0	0	0	1.5	0

*Before treatment.

The present study demonstrates that the application of ABS-G2015 is capable of reducing the numbers of bacteria on surfaces by >99% (2 logs) for 8 weeks after a single treatment (Table 2). Levels of bacteria were reduced by 99.9% (3 logs) at 4 weeks after treatment. Overall, average levels of bacteria never returned to those observed before treatment. Bacterial numbers increased between 8 and 15 weeks posttreatment, but the average bacterial count on all treated surfaces was still <90% (1 log) after 15 weeks. No values >10,000 cfu/100 cm² were detected for 4 weeks after treatment, compared with 25.2% of value measured before treatment, and even after 15 weeks, only 11.1% of the values exceeded this level.

No antibiotic-resistant bacteria were isolated until 8 weeks after the treatment, and then at levels below those measured before the treatment (Table 4). No MRSA or CRE were isolated even after 15 weeks posttreatment, and VRE was isolated only at 8 weeks posttreatment. *C difficile* was not isolated at baseline or after the treatment; however, *C difficile* was isolated in the initial screening used to select the sampling sites (data not shown).

In a recently published study, Boyce et al[18] evaluated two organosilane-based quaternary products for their residual activity in patient rooms in a rehabilitation ward. Neither demonstrated any residual activity over a 4-wk period. The differences found in the present study could be related to the method of application (Boyce et al[18] used microfiber clothes rather than spray application as in the present study), product formulation (formulation of

quaternary ammonium disinfectants plays a major role in their activity against microorganisms and ability to adhere to surfaces[19]), daily cleaning methods by staff, or microbial assay methods (contact plates vs swab and dilution assay).

Based on the results of this study, we recommend applying the treatment every 3-4 months to ensure effective reduction of bac- teria on the treated fomites. Copper surfaces are also antimicrobial and have been demonstrated to reduce exposure to bacteria on surfaces in patent wards.[7] Although directly comparing studies is difficult, the organosilane quaternary ammonium formulation used in the present study appears to be at least as effective in reducing the numbers of bacteria on surfaces and perhaps more effective in reducing the isolation of antibiotic-resistant bacteria on surfaces. Advantages of this treatment over copper surfaces is that it can be easily applied to existing facilities without the need to replace existing equipment, and that its spray application allows treatment of all surfaces (including fabrics), including hard-to-reach surfaces (eg, wall corners, crevices).

A limitation of the study was that some treated items were moved to other locations and could not be found. In addition, the number of rooms occupied by patients over time varied. Strengths of the study include the large area sampled (100 cm^2), use of media designed to optimized recovery of stressed bacteria, and long study duration.

In conclusion, the product assessed in this study was found to have persisted over 15 weeks in reducing the total number of bacteria and antibiotic resistant bacteria on surfaces within an ICU.

Acknowledgment

We thank Daniel A. Moros MD, Craig Grossman, Ingrid Grossman, and Charles Geoffrion for their thoughtful review of this manuscript and design and conduct of the study.

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Study 2

Ellingson et al - CID 2019 –

Impact of a Novel Antimicrobial Surface Coating on Health Care–Associated Infections and Environmental Bioburden at 2 Urban Hospitals

Clinical Infectious Diseases
MAJOR ARTICLE

Impact of a Novel Antimicrobial Surface Coating on Health Care–Associated Infections and Environmental Bioburden at 2 Urban Hospitals

Katherine D. Ellingson,[1] Kristen Pogreba-Brown,[1] Charles P. Gerba,[2] and Sean P. Elliott[3]

[1]Department of Epidemiology and Biostatistics, The University of Arizona College of Public Health, Tucson, Arizona, USA, [2]Department of Soil, Water, and Environmental Science, The University of Arizona, Tucson, Arizona, USA, and [3]The University of Arizona College of Medicine, Tucson, Arizona, USA

Background. Approximately 1 in 25 people admitted to a hospital in the United States will suffer a health care–associated infection (HAI). Environmental contamination of hospital surfaces contributes to HAI transmission. We investigated the impact of an antimicrobial surface coating on HAIs and environmental bioburdens at 2 urban hospitals.

Methods. A transparent antimicrobial surface coating was applied to patient rooms and common areas in 3 units at each hospital. Longitudinal regression models were used to compare changes in hospital-onset multidrug-resistant organism bloodstream infection (MDRO-BSI) and *Clostridium difficile* infection (CDI) rates in the 12 months before and after application of the surface coating. Incidence rate ratios (IRRs) were compared for units receiving the surface coating application and for contemporaneous control units. Environmental samples were collected pre- and post-application to identify bacterial colony forming units (CFUs) and the percent of sites positive for select, clinically relevant pathogens.

Results. Across both hospitals, there was a 36% decline in pooled HAIs (combined MDRO-BSIs and CDIs) in units receiving the surface coating application (IRR, 0.64; 95% confidence interval [CI], .44–.91), and no decline in the control units (IRR, 1.20; 95% CI, .92–1.55). Following the surface application, the total bacterial CFUs at Hospitals A and B declined by 79% and 75%, respectively; the percentages of environmental samples positive for clinically relevant pathogens also declined significantly for both hospitals.

Conclusions. Statistically significant reductions in HAIs and environmental bioburdens occurred in the units receiving the antimicrobial surface coating, suggesting the potential for improved patient outcomes and persistent reductions in environmental contamination. Future studies should assess optimal implementation methods and long-term impacts.

Keywords. health care-associated infections; hospital environment; cleaning; infection prevention; patients' rooms.

Health care–associated infections (HAIs) pose substantial risks to patients and an economic burden to health-care systems. Approximately 1 in 25 patients admitted to a hospital will acquire a HAI, which can lead to longer hospital stays, readmissions, and death [1]. The estimated direct medical cost of HAIs exceeds $30 billion annually in the United States [2], and hospitals face financial penalties from regulators for exceeding HAI thresholds [3]. The frequent use of broad-spectrum antimicrobial drugs has hastened the emergence of *Clostridium difficile* infections (CDIs) and multidrug-resistant organisms (MDROs) in health-care settings [4]. Decreasing the transmission of these pathogens is a priority for health-care providers and public health officials. To this end, the US Department of Health and Human Services has set ambitious 2020 HAI reduction targets, including 30% and 50% reductions in HAIs caused by CDI and invasive methicillin-resistant *Staphylococcus aureus* (MRSA), respectively [5].

Recent systematic reviews have emphasized the role of environmental contamination of hospitals in the transmission of HAIs [6–8]. Pathogens causing HAIs can survive on inanimate surfaces for months and can serve as persistent sources of transmission in the absence of control measures. Further, health-care personnel can contaminate their hands and gloves with MDROs, *C. difficile*, and other common HAI pathogens after touching contaminated surfaces [9, 10]. Few products offer persistent efficacy, so surfaces can be re-contaminated immediately after cleaning [11]. Even with protocols in place for terminal cleaning of patient rooms, patients face elevated risks of HAIs from organisms left on surfaces by prior room occupants [12, 13]. In addition, terminal cleaning does not prevent the room from becoming re-contaminated with microbes within 24 hours of rooming a new patient [14, 15]. These

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Correspondence: K. D. Ellingson, Department of Epidemiology and Biostatistics, The University of Arizona College of Public Health, 1295 N. Martin Avenue, Drachman Hall, Campus PO Box 85724-5163, Tucson 85724, AZ (kellingson@email.arizona.edu).

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challenges have led to a call for research on innovative technologies that confer persistent antimicrobial activity, with evaluations of the clinical impacts on patient outcomes [16].

Such an emerging technology is a transparent, antimicrobial surface (AMS) coating that can be applied by an electrostatic spray procedure. The mechanism for persistent antimicrobial activity is a quaternary ammonium polymer coating that disrupts the cell membranes of microbes, leading to cell lysis. The coating can minimize bacterial survival on surfaces for up to 15 weeks by bonding to the surface and creating a protective antimicrobial barrier [17]. This product can be applied to most surfaces—including bedframes, mattresses, medical equipment, furniture, walls, ceilings, windows, doors, hallways, and curtains—after a room is cleaned. The active ingredient reduces both bacteria and fungus [18, 19]; although it does not kill spores, it influences both surface charge and hydrophobicity, which enhance adhesion to surfaces and could make spores less likely to be aerosolized or transferred to other surfaces [20, 21].

In this study, we used a multicenter, nonrandomized, pre-post study design with contemporaneous control groups to assess the impact of AMS coating application on HAIs and surface contamination. Our objectives were: (1) to assess changes in hospital-onset HAIs in the year before and after application of the AMS coating; and (2) to identify changes in microbial burdens and clinically relevant pathogen presences on surfaces, relative to the AMS coating application.

METHODS

Study Sites

The study was conducted in 2 hospitals in a large, American city, hereafter referred to as Hospital A and Hospital B. Hospital A has 250–300 licensed beds, a case mix index of 1.43, and certification for Level III trauma care. Hospital B has over 350 licensed beds, a case mix index of 1.80, and certification for Level I trauma care. Both hospitals have cardiac, emergency, surgical, and intensive care unit (ICU) services. Only Hospital B has neonatal ICU (NICU), oncology, and solid organ transplant services. At each hospital, 3 units were nonrandomly selected for AMS coating application. Non-application units were considered control units. At Hospital A, 1 medical ICU and 2 medical wards were selected for AMS coating application; at Hospital B, 1 medical ICU, 1 neurological ICU, and 1 transplant step-down unit were selected for AMS coating application.

The Western Institutional Review Board reviewed the study protocol and determined the study to be exempt from full human subjects review as a quality improvement initiative. The company that invented and produces the AMS coating initiated the study with both hospitals. All environmental sampling and microbiology testing were performed by an independent laboratory. All analyses of HAI data were conducted by independent researchers.

Product Application

Certified technicians followed a uniform protocol for the surface preparation and application of AMS coating, and a manufacturer representative monitored all applications for quality control. Prior to an application, the surfaces were prepared with a solution containing a mild emulsifying agent on all hard, high-touch surfaces—including keyboards, countertops, railings, and chairs—to remove any buildup of organic matter. Technicians then applied the AMS coating with an electrostatic spray applicator to all hard and soft surfaces in the selected treatment units. Common areas were treated at night, when minimally staffed and free from visitors. For patient rooms, technicians coordinated with hospital personnel to enter rooms immediately following a discharge and terminal cleaning. For mobile items—including patient beds, intravenous poles, and wheelchairs—a barcode was placed on the item to indicate when the AMS coating had been applied.

Technicians applied the surface coating 3 times over the course of the study, approximately once every 4 months. The treatment of "fixed" items occurred each time, while mobile items were treated if they were in the select room or common area at the time of application. At Hospital A, technicians applied AMS coating to 104 single-patient rooms and 54 common areas, including nurses' stations, staff lounges, and family waiting rooms. In Hospital B, technicians applied the product to 108 single-patient rooms and 114 common areas. All fixed and mobile items in the room were treated as they were positioned in each room. A complete application took approximately 4 weeks (20 business days). Prior to and following the application of the AMS coating, hospital staff maintained their normal, daily cleaning schedule in all areas, which involved using reusable cloths and disinfecting with hospital-grade disinfectants, such as bleach or quaternary ammonium compounds.

Health Care–Associated Infections

To quantify the impact of the AMS coating on HAIs, we assessed changes in the incidences of hospital-onset MDRO bloodstream infections (BSI) and hospital-onset CDIs. Specifically, we examined monthly incidences (infections/1000 patient days) in the 12-month pre- and post-application periods for units receiving AMS coating (application units) and units not receiving AMS coating (control units). Control units accounted for underlying HAI trends not associated with AMS coating. Total patient days for the 12 months pre- and post-application were similar at Hospitals A and B (Table 1).

As part of routine HAI monitoring, infection preventionists at each hospital tracked HAIs per National Healthcare Safety Network (NHSN) protocols [22]. The NHSN protocols specify laboratory identification, de-duplication, and internal validation procedures for the monthly collection of MDRO-BSI and CDI metrics [23]. We used hospital-onset MDRO-BSI and CDI data collected from October 2015 through December 2017 at Hospitals A and B (Figure 1). We considered rates

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Table 1. Distribution of Units, Rooms, and Patient Days Relative to Antimicrobial Surface Coating Application at Hospitals A and B

Hospital	Unit Status	Units	Rooms	Patient days (Pre)	Patient days (Post)
A	Application	3	104	29 345	29 627
	Control	5	>150	42 616	43 810
B	Application	3	108	28 451	28 991
	Control	6	>250	52 019	53 090

Abbreviations: Post, 12-month post-application periods; Pre, 12-month pre-application period.

of hospital-onset MDRO-BSI and CDI for 12-month pre-application and 12-month post-application periods. We excluded a 2-month application period at Hospital A and a 3-month application period at Hospital B, because these periods could not be categorized cleanly as pre- or post-application periods. Also, we excluded 1 control unit at Hospital B—the NICU—since NICUs do not track CDI per NHSN protocols. No changes in infection prevention or cleaning protocols occurred throughout the pre- and post-application study periods.

We calculated incidence rate ratios (IRRs) to quantify changes in the incidences of hospital-onset MDRO-BSI, CDI, and pooled infections (MDRO-BSI + CDI) relative to product application periods for application and control units at each hospital. We used general estimating equation regression modeling to generate IRRs, 95% confidence intervals (CIs), and *P* values. We specified the general estimating equation models to accommodate a Poisson distribution with patient-days as an offset, repeated observations over time by unit, and a first-order autoregressive correlation structure to account for nonindependence of observations by month. To generate separate IRRs for application and control units, we modeled monthly infection rates by their pre-post application status. We ran separate models for each outcome (both MDRO-BSI and CDI) at each hospital, as well as combined models (pooled MDRO-BSI and CDI). Finally, we created models including both application and control units, with interaction terms to assess whether pre-post application differences were significantly different by unit type (ie, a difference-in-difference analysis). In the following equation, the interaction term is characterized as $\beta 3$ and interpreted as an IRR.

$$\gamma HAI = \beta 0 + \beta 1\ (Pre - Post\ application\ period) + \beta 2(Application - Control\ Unit) + \beta 3\ (Pre - Post * Application - Control) + \varepsilon$$

Environmental Sampling

A technician from an independent laboratory conducted all pre-application and post-application environmental sampling at Hospitals A and B in application units only. Sampling of surfaces and items in patient rooms occurred following patient discharges but prior to terminal cleaning and a subsequent AMS coating application. Post-application sampling took

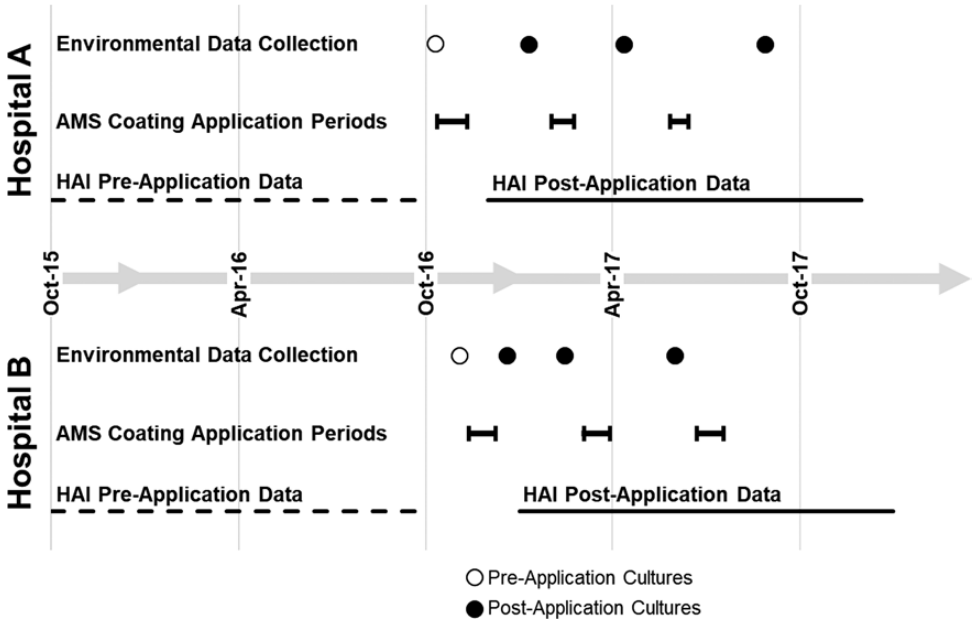

Figure 1. Timeline for application of product, collection of environmental data, and collection of hospital-onset multidrug-resistant organism and *Clostridium difficile* data at Hospitals A and B. Abbreviations: AMS, antimicrobial surface; HAI, health care–associated infection.

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place at approximately 11 weeks following each AMS coating application. This post-application sampling interval was determined based on previous efficacy studies of AMS coating [17]. At Hospital B, the technician also sampled at 4 weeks post-treatment during the first application and did not sample at 11 weeks following the third application (Figure 1). Prior to the surface coating application, the technician collected 32 environmental samples at Hospital A and 133 at Hospital B. Over 3 post-application collection periods at each hospital, the technician collected 342 samples at Hospital A and 399 at Hospital B.

The laboratory technician sampled areas of 100 cm^2 using a sponge stick containing Letheen broth (3M, St Paul, MN) to neutralize any residual disinfectant. After collection, the samples were immediately placed on ice packs and sent overnight to the MicroChem Laboratories (Round Rock, TX). Upon receipt, the broth was extracted from the sponge stick by manual agitation, and extracted broth was assayed using selective media for isolation of the various bacteria. Samples were cultured for total aerobic bacteria on Trypticase Soy Agar (Hardy Diagnostics, Santa Maria, CA) by the pour plate method.

The plates were incubated for 5 days at 24±5°C and the resulting colonies were counted. Vancomycin-resistant *Enterococcus* (VRE) and carbapenem-resistant *Enterobacteriaceae* (CRE) were assayed using Chrom agar media, as previously described [24, 25]. MRSA was assayed according to the methods described by May [26], and *Clostridium difficile* was assayed on brain-heart infusion agar (Hardy-Criterion, Santa Maria, CA) with yeast extract (Van Waters and Rogers Company, Seattle, WA) and horse blood agar (Hemostat Laboratories, Dixon, CA) [27]. The limit of detection for total bacteria was 1.00E+01. The lower limit for the selective plates was dependent on the sample volume and ranged from 1.40E+01 to 2.6E+01.

Environmental samples were evaluated for total bacterial colony forming units (CFUs) and for the presence of 4 clinically relevant pathogens: CRE, MRSA, VRE, and *C. difficile*. For mean CFU counts of total heterotrophic bacteria, arithmetic means were calculated and nonparametric (Mann-Whitney) statistical tests were used to compare means. To determine the percent of samples positive for select pathogens, the number of surfaces positive for a clinically relevant pathogen was divided by the total number of sites sampled. A Student's *t* test was used to determine differences in percentages of positive sites in the pre- versus post-application periods.

RESULTS

Health Care–Associated Infections

Across both hospitals, there was a 36% decline in pooled HAIs (hospital-onset MDRO-BSI and CDI) following an application of ABS coating (IRR, 0.64; 95% CI, .44–.91). In control units, there was no decline in HAIs over the same period (IRR, 1.20; 95% CI, .92–1.55). The difference in IRRs for application and control units for pooled HAI was significant ($P = .005$).

In application units at Hospital A, there were significant HAI reductions following applications of ABS coating, including a 52% reduction in pooled HAIs (IRR, 0.46; 95% CI, .38–.61), a 54% reduction in MDRO-BSIs (IRR, 0.46; 95% CI, .28–.77), and a 47% reduction in CDIs (IRR, 0.53; 97% CI, .38–.74); there were no reductions in HAIs in control units (Table 2; Figure 2A). The differences in IRRs for application and control units were significant for pooled HAIs (0.002) and borderline significant for MDRO-BSIs (0.125) and CDIs (0.119).

In application units at Hospital B, there was a 37% reduction in CDIs following AMS coating (IRR, 0.63; 95% CI, .45–.88) and were nonsignificant reductions in MDRO-BSIs and pooled HAIs (Table 2; Figure 2B). In control units, there were no statistically significant differences in MDRO-BSIs, CDIs, or pooled HAIs during the same time period. For each of these outcomes, there were greater reductions of infection rates in application

Table 2. Number and Rate of Hospital-onset Infections in the Surface Application and No Application Units at Hospitals A and B

Hospital	Unit Status	Outcome	Number of Cases (Pre)	Rate Per 1000 Pt. Days (Pre)	Number of Cases (Post)	Rate Per 1000 Pt. Days (Post)	*P* Value for Pre-post Difference
Hospital A	Application	Pooled	47	1.60	23	.78	<.001
		MDRO-BSI	32	1.09	15	.51	.003
		CDI	15	.51	8	.27	<.001
	Control	Pooled	24	.56	26	.59	.794
		MDRO-BSI	14	.33	13	.30	.775
		CDI	10	.23	13	.30	.649
Hospital B	Application	Pooled	75	2.64	57	1.97	.192
		MDRO-BSI	42	1.48	36	1.24	.574
		CDI	33	1.16	21	.72	.007
	Control	Pooled	52	1.00	61	1.15	.196
		MDRO-BSI	25	.48	37	.70	.066
		CDI	27	.52	24	.45	.545

The *P* values were on incidence rate ratios generated by general estimating equation regression models controlling for nonindependence and autocorrelation.
Abbreviations: BSI, bloodstream infection; CDI, *Clostridium difficile* infection; MDRO, multidrug-resistant organisms; Pooled, combined MDRO-BSI and CDI; Post, 12-month post-application periods; Pre, 12-month pre-application period; Pt., patient.

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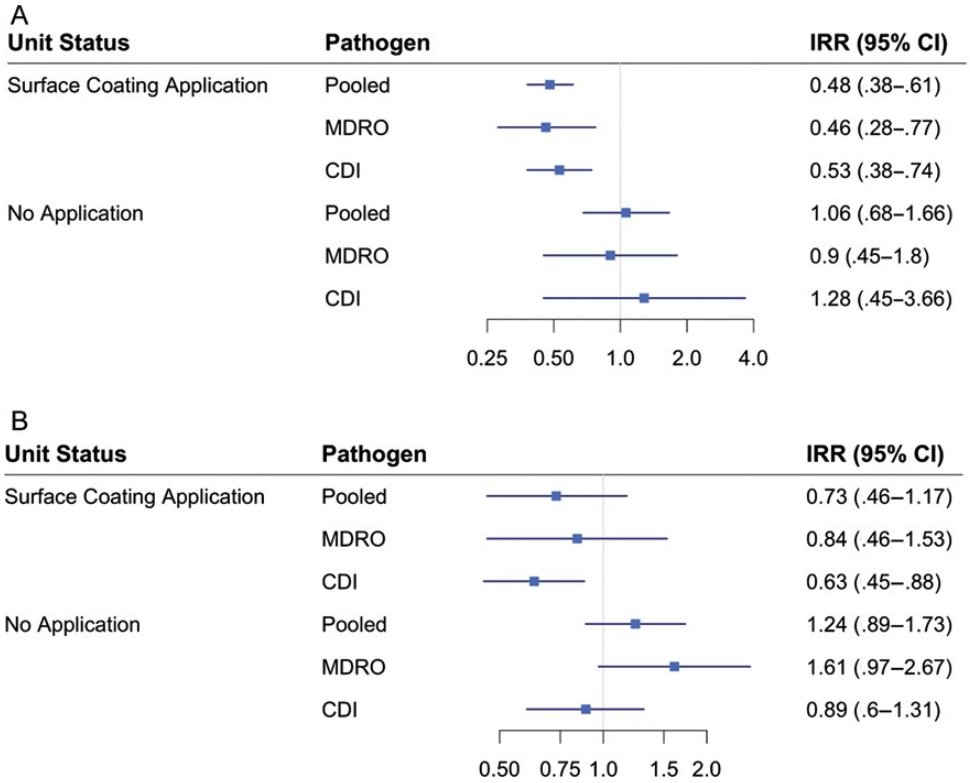

Figure 2. IRRs and 95% CIs are displayed on a forest plot for MDRO, CDI, and pooled health care–associated infection rates at (*A*) Hospital A and (*B*) Hospital B. IRRs less than 1 indicate reductions in the post-application period. Abbreviations: CDI, *Clostridium difficile* infection; CI, confidence interval; IRR, incidence rate ratio; MDRO, multidrug-resistant organism.

versus control units, although these differences were borderline significant ($P = .065$ for pooled HAIs; $P = .120$ for MDRO-BSIs; $P = .162$ for CDIs).

Environmental Bioburden

There were statistically significant decreases in total CFU levels at both hospitals following applications of the AMS coating (a 79% decrease for Hospital A and a 75% decrease in Hospital B). At Hospital A, sampling occurred at baseline and at 11 weeks following each of the 3 applications. For total bacterial CFUs, the mean baseline level of 208.0 CFU/cm^2 decreased to 74.6 CFU/cm^2 following the first application. That decrease continued following the second application (40.4 CFU/cm^2) and third application (15.3 CFU/cm^2; $P < .0001$, comparing the baseline to all post-application periods combined).

At Hospital B—which used a slightly different sampling protocol than Hospital A, with sampling at 4 and 11 weeks after the first application and 11 weeks after the second application—the total bacterial CFU level had decreased from a mean baseline level of 221.9 CFU/cm^2 to 30.3 CFU/cm^2 at 11 weeks after the first application and decreased further, to 16.91 CFU/cm^2, at 11 weeks after the second application.

At both hospitals, the percent of sites positive for clinically relevant pathogens decreased (Figure 3). For Hospital A, of the 32 samples collected at baseline, the number of positive sites ranged from 2 (*C. difficile*) to 12 (MRSA). When all post-application sampling results were combined and compared to the pre-application levels, the percentage of positive sites decreased for each pathogen (Figure 3). In Hospital A, *C. difficile* decreased from 6.3% of sites positive to 0.0% positive; CRE decreased from 15.6% to 4.3% ($P < .0001$); VRE decreased from 12.5% to 4.3% ($P = .042$); and MRSA decreased from 37.5% to 12.4% ($P = .0001$). For Hospital B, *C. difficile* decreased from 3.0% positive sites at baseline to 0.4% at follow-up ($P = .005$); CRE decreased from 10.5% to 4.6% ($P = .009$); VRE decreased from 15.0% to 3.1% ($P < .0001$); and MRSA decreased from 18.1% to 14.4% ($P > .05$).

DISCUSSION

In this first study to assess the impact of AMS coating on HAI rates, we observed significant HAI reductions in units receiving the AMS coating and no impact in control units across both hospitals. Hospital A showed a clearer distinction in HAI rates between application and control units than Hospital B, suggesting a variable impact across facilities. The increase in hospital-onset MDRO rates in control units at Hospital B suggests that other factors may have increased the overall infection risk during the application period, despite noted decreases

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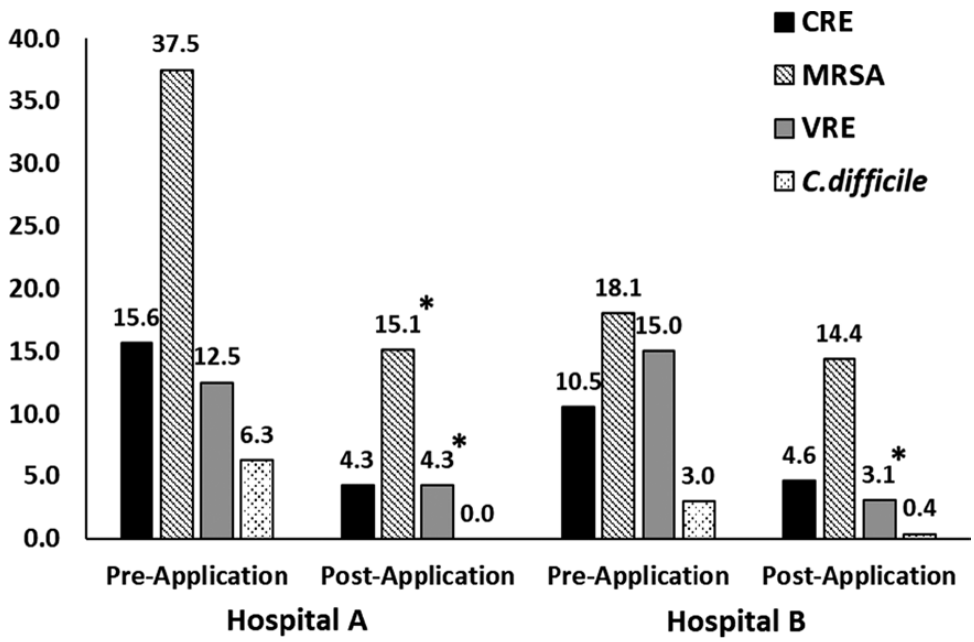

Figure 3. Percent of sites positive for select, clinically relevant pathogens before the application of AMS coating (labeled as "Pre-Application"), compared to sites positive after the application of coating (labeled as "Post-Application") at Hospitals A and B. *Indicates a statistically significant difference from baseline at the $P < .05$ level. Abbreviations: AMS, antimicrobial surface; *C. difficile*, *Clostridium difficile*; CRE, carbapenem-resistant *Enterobacteriaceae*; MRSA, methicillin-resistant *Staphylococcus aureus*; VRE, vancomycin-resistant *Enterococcus.*

in the environmental bioburden. Overall, decreases in HAIs in application units were accompanied by decreases in environmental bioburdens and clinically significant pathogens in those units treated with the ABS coating.

Inanimate surfaces are known to play a role in the transmission of HAIs in the health-care environment [16, 28]. Cleaning and disinfection of surfaces is an effective approach to reducing the spread of pathogens; however, surfaces are often not adequately cleaned, and recontamination can occur within minutes [16]. Many commercial products demonstrate the ability to reduce the bacterial load in clinical settings, yet the clinical translations of these products have not been well described [29]. In this study, we demonstrated a reduction in HAIs, concurrent with a reduction in bacterial loads, following the application of the AMS coating. While the association between a reduced bacterial load and reduced HAIs might appear obvious, the determination of the bacterial presence in a clinical setting is imperfect due to several factors (ie, sampling error, bacterial load limits of detection, persistence of bacteria in/on under-treated areas of the clinical setting, variability in cleaning protocol adherence, variability in clinical practices). Thus, a patient might still be at risk for acquiring a HAI despite an apparent reduction of the bacterial load in a clinical setting.

A limitation of this study is that no environmental data were collected in control units. Another potential limitation is the possibility that lower baseline HAI rates in control units would require a longer study period to demonstrate significant HAI reductions. However, this study did demonstrate statistically significant reductions in both environmental contamination and HAIs in the application units, while the HAI rates in the control units appeared to increase, though not significantly. Finally, at Hospital B, the decreases in MDRO-BSIs were not significant in the application units, although MDRO-BSIs increased nonsignificantly in the control units. Several explanations may account for these findings. First, we encountered mobility of such items as hospital beds, patient-assist devices, intravenous poles, and pumps and monitoring devices. Attempts to track and treat mobile assets were compromised by a lack of protected time and space for the assets when not in use. Finally, this study design prioritized patient care over the study implementation, which impacted the precision of the timing for treatments and sampling in some cases.

Our study is further limited by a lack of monthly, unit-specific infection prevention and antimicrobial use data, which could have affected hospital-onset MDRO-BSI and CDI rates during the pre- and post-application periods. However, at Hospital A, we did obtain hospital-wide hand hygiene data, which showed that hand hygiene decreased from 90% in the pre-application period to 56% in the post-application period. This finding suggests that unmeasured increases in hand hygiene did not account for infection declines noted in the study; in fact, declines in hand hygiene should bias findings towards the null in the application units. At Hospital B, unit-specific infection prevention process data demonstrated declines in hand hygiene and isolation precaution adherence for both the application and control units. These declines could explain the

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limited impact of the ABS coating at Hospital B, and suggest that unmeasured enhancements in infection practices do not explain declines in CDI rates at Hospital B relative to the ABS coating application.

Future studies should incorporate the knowledge gained in this study to more directly focus the benefits, scalability, and cost-effectiveness of AMS coating applications. Future studies need to better define changes in other sources of HAI risk and to better quantify the independent impacts of products like AMS coating in complex health-care environments. Also, studies of applications in high-touch, key patient entry points, such as the emergency department, urgent care centers, and long-term care facilities, will be important in understanding the potential of antimicrobial surface coating in preventing HAIs.

Notes

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Disclaimer. The study design was developed by ABS and the technology is the sole property of ABS. The study was executed in collaboration with clinical and administrative leaders at Methodist. Environmental sampling and testing were conducted by a third party GLP-certified lab. The Infection data were collected, aggregated, and provided by the Methodist Infection Prevention staff as part of their ongoing infection rate monitoring processes.

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Potential conflicts of interest. C. P. G. has served as an unpaid advisor to ABS. K. P.-B. and K. E. received consulting fees for statistical analyses from ABS. All other authors report no potential conflicts of interest. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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Study 3

Gerba Transit Whitepaper

-Long Term Reduction of Bacteria on Surfaces in Public Buses

the department of
Soil, Water and Environmental Science
THE UNIVERSITY OF ARIZONA

Long Term Reduction of Bacteria on Surfaces in Public Buses

ABSTRACT

Use of public transport may serve as a vehicle for the transmission of infectious disease. The goal of this study was to assess bacterial loads on high touch areas within municipal buses and assess the use of a new coating comprising silicon-oxide bonds and titanium-oxide bonds provided by Allied BioScience, Inc on the long term suppression of bacterial numbers on high touch areas within the buses. Public buses were tested on selected sites for heterotrophic bacteria. The most contaminated sites were the driver's compartment and the fare box. One group of busses was then treated with the disinfectant and another was not. After 30 days statistically significantly fewer bacteria where present on the treated buses.

KEYWORDS

Public transportation, bacteria, fomites, buses, hygiene, disinfection

CORRESPONDING AUTHOR

Charles P. Gerba, Ph.D.
Department of Soil, Water and Environmental Science
University of Arizona
Tucson, AZ 86721 USA

INTRODUCTION

A route of transmission of cold, flu, diarrhea and other common infections is through contact with surfaces contaminated with infectious microorganisms (pathogens) (Boone and Gerba, 2007). Contamination occurs by settling of droplets from coughs and sneezes onto surfaces, and by touching of surfaces with hands contaminated with pathogens. The pathogens then contaminate the hands of the next person who touches the same surface, and when they bring their hands to their eyes, nose, or mouth infection can result. Mass transportation systems create an environment in which large numbers of persons on a daily basis share space and interact with surfaces found within system vehicles. A recent study in the United Kingdom demonstrated an increase of respiratory infections (colds and flus) to persons if they had ridden in a bus or streetcar five days previously (Troko et al., 2011).

Application of disinfectants on surfaces has been shown to reduce absenteeism and illness in schools (Bright et al., 2010). Unfortunately surfaces have to be disinfected on a regular basis to be effective. This is difficult in mass transportation when large numbers of individuals may be using the same vehicle in a day. Surfaces may become recontaminated throughout the service day of the vehicle. Treatment of surfaces with a product that could reduce the microbial load on a continuous basis would be ideal in these situations.

This study was designed to assess the effectiveness of a coating comprising silicon-oxide bonds and titanium-oxide bonds in suppressing the number of bacteria on surfaces within a public bus.

MATERIALS AND METHODS

In a recent study done at a public bus company, forty buses out of 220 were sprayed with a new product as a test. From these 40, seven buses were selected at random as an "experimental" group that was treated with materials that form a coating comprising silicon-oxide bonds and titanium-oxide bonds obtained from Allied Bioscience, 100 Crescent Court, Suite 450 Dallas, TX. Another seven buses, selected from the180 busses that were not sprayed, were selected at random as a "control" group. All busses received only routine cleaning at the end of the work day. Routine cleaning consisted of general sweeping, removal of trash and wiping down railings and other surfaces with a commercial detergent. Prior to any treatment, both groups of buses were tested for heterotrophic bacteria on various surfaces in order to establish a baseline profile of each bus. All buses were given a four-digit code as not to reveal the treated from the untreated buses. In an average day each bus transported approximately 400 persons.

Surface samples were taken at five locations in each of the fourteen busses for heterotopic bacteria: entry railing, fare box, driver compartment, interior railing, and seat back. Samples were taken at the end of the working day after the bus returned to the transit facility but before they were cleaned by night maintenance workers. Samples were collected in all of the busses before the intervention and then 30 days later.

Sites were sampled with a Spongestick (3M, St. Paul, MN) containing a neutralizing broth to neutralize any disinfectant that may have been on the sampled area. Approximately 150 cm^2 of the surface was sampled at each selected location in the bus. All samples were inserted in individual bags that were labeled with a random number code. This procedure was used to prevent workers in the microbiology laboratory from knowing which samples belonged to which buses, thus establishing a blind study. Once the laboratory provided the culture results, the codes were used to assign values to the appropriate buses and locations within those buses. The numbers of heterotrophic bacteria (HPC) were determined on R2A media (Difco, Sparks, MD) using the spread plate method. Samples were diluted using physiological saline for assay of dilutions. All dilutions were assayed in duplicates. The agar plates were then incubated at room temperature (~24 ^{o}C) for five days and the resulting colonies of bacteria counted.

The bacterial concentrations used to compare the treated vs. untreated measurements for the different locations in the buses proved to have a distribution other than normal (i.e. a bell shaped distribution curve); and hence the bacterial concentrations were transformed using log base 10 (i.e. 100 = 2, 1,000 = 3, etc.). The log base 10 transformed bacterial concentrations used to compare treated vs. untreated measurements proved to be normally distributed, with similar variances and without outliers which are the conditions necessary to conduct analysis of variance (ANOVA). Analysis of variance was performed on the log base 10 transformed data using the *F* statistic and a two sided rejection region of 5% (Ott, and Longnecker. 2001)

RESULTS

The number of bacteria per 150 cm^2 ranged from 40 to 1,480,000 colony forming units (CFU) on the surfaces tested from all the buses before the intervention. Arithmetic and geometric means including standard deviations of bacteria concentrations on the areas tested in the buses are shown in Table 1. The statistical analysis (ANOVA) indicated that there was no statistical difference in the numbers of bacteria in the busses that were selected for treatment and those that were not at the beginning (baseline data) of the study with a *p*-value of 0.315. After 30 days, representing an average bus use by a total of 12,000 passengers during the study period, the same buses were resampled (Table 2). The number of bacteria on the surfaces in the treated buses was significantly less than that in the untreated buses (*p*-value = 0.005). On average there were 93% fewer bacteria on the surfaces in the treated buses vs. the untreated buses based on geometric mean and 62% based on arithmetic mean.

The goal of this study was to demonstrate if there was a significant difference between the bacterial load in the bus interior of the treated and untreated buses. The number of samples obtained at each individual location within the vehicle was not chosen to be able to demonstrate significance at each individual sampled site. However, with the exception of the entry railing, the bacterial burden at all treated sites was reduced as compared to the untreated sites (Table 3). The greatest difference between treated and untreated buses in bacteria numbers was in the driver's compartment where there were fewer than 99.8% bacteria in the treated busses. This difference was highly significant (*p*-value = 0.007).

DISCUSSION AND CONCLUSIONS

Use of public transport (trains, planes, buses, ships) has been shown to play a role in the transmission of infectious diseases. The most studied have been cruise ships which have had to deal with large recurring outbreaks of norovirus (Wikswo et al., 2011). Containment of passengers for several days on the same transport makes such transmission more easily documented than commuters on airplanes and buses. Still air travel has been shown to present a risk of norovirus and respiratory infection among the passengers (Thornley et al., 2011). Studies of trains and buses suggest that transmission of respiratory infections can occur (Mohr et al., 2012), but data is limited largely to tuberculosis, since it is more likely to be diagnosed. However, a recent study in the United Kingdom demonstrated an increase of respiratory infections (colds and flus) to persons if they had ridden in a bus or streetcar five days previously (Troko et al., 2011). Luksamijarulkul et al. (2004) found elevated levels of bacteria (>550 m^3) in buses in Thailand. We are not aware of any previous published studies on the occurrence of microorganisms on surfaces in buses in the United States.

Total bacterial numbers or heterotrophic bacteria on hard surfaces are used as a general measure of the hygienic quality of public surfaces (Reynolds et al., 2005) and the effectiveness of cleaning and disinfection of interventions (Bright et al., 2010). Reynolds et al. (2005) found detectable levels of protein on 61% of, and bodily fluids (urea, hemoglobin, mucus/sweat) on 41% of armrests/handles in public busses. Viruses and bacteria that cause respiratory infections and gastroenteritis can be transmitted by contact

with contaminated bodily fluids. Since hundreds of people may be expected to use the bus throughout the day, contamination of surfaces throughout a bus can be expected.

The greatest number of bacteria was found to be on the fare box, entrance railing and the driver's compartment. Both the fare box and entrance railings were probably the most touched areas by passengers. Drivers are present throughout the operation of the bus continually interacting with surfaces within the driver's compartment. Although somewhat isolated from the passenger's transmission of infectious organisms on the surfaces, drivers' exposure could occur during breaks and shift changes.

At the beginning of the study there was no statistical difference between levels of bacteria in the buses selected for study. However, the concentration of bacteria was significantly less in the interior of the treated vs. untreated buses after 30 days of use. On average there were 93% fewer bacteria on the interior surfaces of the treated buses in comparison to the same surfaces of the untreated busses. The greatest reductions occurred in the driver's compartment and the least on the entrance rail. The large amount of surface friction from hand contact to the entrance rail may be the reason for no difference at this site compared to the others within the bus. This suggests that this site may need to be treated differently than the other sites within the bus. Although not always statistically significant, lower concentrations of bacteria were found at all interior sites of treated buses when compared to the untreated buses.

The results of this study demonstrate that reduced levels of bacteria still occur in heavily used public buses 30 days after treatment with materials that form a coating comprising silicon-oxide bonds and titanium-oxide bonds. The product's effectiveness varied from site to site probably reflecting the degree of contact with that site by passengers. Reapplication of the product at more regular frequencies at high touch sites is probably necessary to keep bacterial numbers lower at these sites.

In conclusion, this study demonstrated that application of materials that form a coating comprising silicon-oxide bonds and titanium-oxide bonds to public buses resulted in significantly lower levels of bacteria after 30 days as a result of a onetime application.

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Table 1

Average number of bacteria per 150 cm^2 in treated vs. untreated buses at baseline (before treatment of experimental buses)

Sample Type	Sample Size (N)	Arithmetic Mean	Standard Deviation	Geometric Mean	Standard Deviation of Log_{10} Transformed Measurements
Treated	35	57,114	254,392	783	1.13
Untreated	35	5,584	13,842	1,336	0.75

Table 2

Average number of bacteria per 150 cm^2 in treated vs. untreated buses after 30 days

Sample Type	Sample Size (N)	Arithmetic Mean	Standard Deviation	Geometric Mean	Standard Deviation of Log_{10} Transformed Measurements
Treated	35	867,754	2,563,567	5,870	1.69
Untreated	33*	2,285,438	4,391,445	83,588	1.58

*data for two sites were not available

Table 3

Average number of bacterial per 150 cm^2 at specific tested sites in treated and untreated buses

Sampled Site	Sample Type	Sample Size (N)	Geometric Mean	percent Reduction	*p*-value
All Locations in Each Bus	Treated	35	5,870	93.0	0.005
	Untreated	33	83,588		
Drivers Compartment	Treated	7	815	99.8	0.007
	Untreated	6	364,738		
Entrance Railing	Treated	7	151,053	0.0	0.832
	Untreated	7	91,451		
Seat Backs	Treated	7	687	97.8	0.071
	Untreated	7	31,022		
Interior Railing	Treated	7	2,265	88.1	0.222
	Untreated	7	19,024		
Fare Box	Treated	7	36,356	88.2	0.253
	Untreated	6	308,280		

Study 4

Gerba etal-medRxiv-2020-

A continuously active antimicrobial coating effective against Human Coronavirus 229E

RESEARCH, DISCOVERY & INNOVATION
Water & Energy Sustainable Technology Center

Study Title

Antimicrobial surface testing of ABS antimicrobial coating, *SurfaceWise*2™, against Human Coronavirus 229E

Test Method

Modified ASTM International Method E1153
Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces

ASTM E1153: General Information

ASTM International is an internationally recognized organization that develops and publishes product and testing standards methodology, many of which are used by the EPA to evaluate claims. ASTM E1153 is a quantitative method used to evaluate the efficacy of sanitizers on pre-cleaned inanimate, nonporous, non-food contact surfaces. Normally, products are evaluated against a representative Gram-negative and Gram-positive organism with a maximum contact time of 5 minutes. This method has been modified to directly assess the efficacy of ABS-continuously active antimicrobial surface coatings against human coronavirus. Briefly, the antimicrobial coating is applied to carriers first using an electrostatic spray application, then test organisms are inoculated, and efficacy is evaluated after a 120 minute contact time.

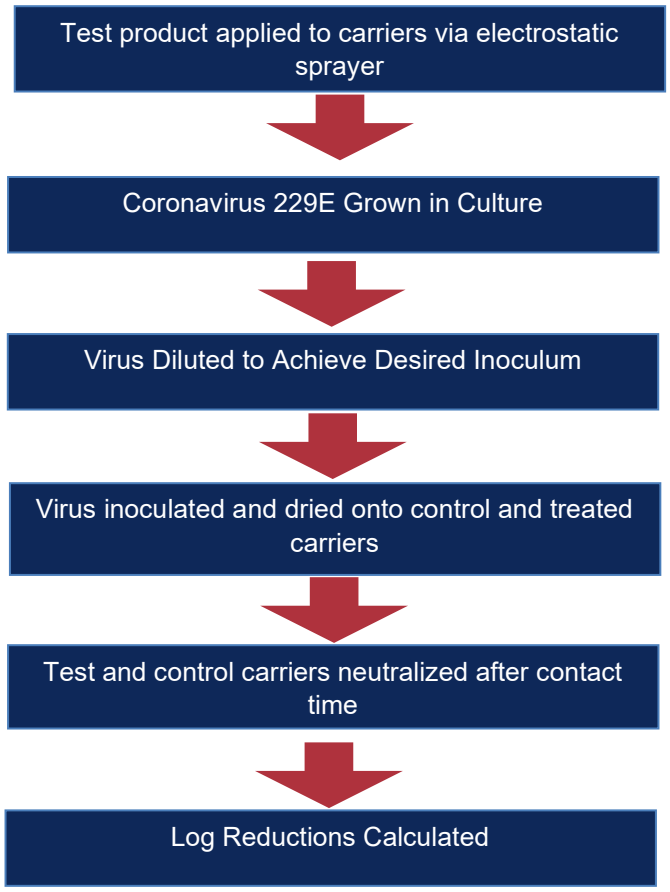
Test Substance Information

Manufacture date: March 29, 2020
Test substance evaluated as a dry, treated surface; product was applied using an electrostatic sprayer.

Test Microorganism Information

Human Coronavirus strain 229E (ATCC VR-740) is an enveloped virus belonging to the *Coronaviridae* family of viruses that causes mild respiratory illness and is spread from person to person through droplets. It has been well documented that this strain can survive and remain infectious on surfaces for up to 3 hours, suggesting that hard-surfaces could be another vector of transmission for coronaviruses. A number of registered disinfectant products with varying active ingredients are capable of inactivating coronaviruses. The host cell line used for assessing infection of strain 229E is MRC-5 (ATCC CCL-171). After exposure of virus to a test substance, the virus is added to the mammalian host cell and allowed to incubate for a period of 5-7 days prior to assessing virus inactivation.

Diagram of the Procedure



Summary of the Procedure

- Test product was applied to stainless steel carriers using an electrostatic sprayer.
- The test microorganism is prepared by growth in liquid culture medium and is subsequently diluted to achieve an inoculum that satisfies the requirements of the test method.
- 0.100 mL of viral suspension is inoculated onto stainless steel carriers at ambient temperature and incubated for a 120 minute contact time.
- At conclusion of the contact time, test carriers are swabbed using a cotton-tipped swab saturated with neutralizer broth. The swab was added to 1 mL of neutralizer broth, and then vortexed to release any surviving microorganisms from the swab.
- Appropriate dilutions of neutralized control and test conditions are made in 0% FBS MEM and plated in 2% FBS MEM.
- The effect of the test substance is determined by comparing the amount of viral cytopathogenic effects (CPE) formed between control and test conditions and calculating the log reduction.

Passing Criteria

ASTM International defines passing criteria to be a 3 Log_{10} or 99.9% reduction in the treated test carriers when compared to the control carriers.

Testing Parameters used in this Study

Carrier Size: 2” x 2” stainless steel
Culture Media: 2% FBS MEM
Inoculum concentration: ~$5x10^4$
Carrier Dry Temp: Ambient
Contact Temp: Ambient
Contact Times: 10 minutes, 120 minutes
Plate incubation temperature: 35°C

Replicates: 3
Culture Growth Time: N.A.
Inoculum area: 2” x 2”
Carrier Dry Time: xx
Number of sprays: N/A
Neutralizer and Volume: 1 mL D/E + Sephacryl G-10
Plate incubation time: 7 days

Calculations

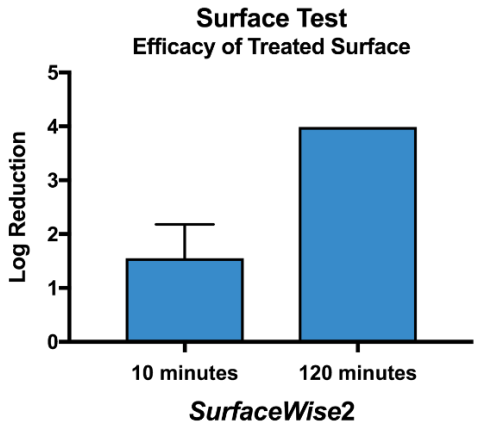
$$Log_{10} \text{ Reduction} = Log \left(\frac{B}{A}\right)$$

Where:

B = $TCID_{50}$ from the test carriers after the contact time
A = $TCID_{50}$ from the control carriers after the contact time

Results

Test Organism	Test Sample	Contact Time	$TCID_{50}$ / carrier	Mean	Log Reduction
Coronavirus 229E	Control - PBS	10 minutes	9.28E+04	5.51E+04	N/A
			4.31E+04		
			2.94E+04		
	ABS-*SurfaceWise2*	10 minutes	2.94E+02	2.51E+03	1.34
			2.94E+03		
			4.31E+03		
	Control - PBS	120 minutes	6.32E+04	6.18E+04	N/A
			2.94E+04		
			9.28E+04		
	ABS-*SurfaceWise2*	120 minutes	<6.32	<6.32	>3.99
			<6.32		
			<6.32		



7 Tolerances

SECTION 166.20(a)(6): EXPECTED RESIDUES FOR FOOD USES

N / A Not intended for on crop use.

8 Miscellaneous

RISK ASSESSMENT for TRIMETHOXYSILYL QUATS

As active ingredients trimethoxysilyl quats are used as materials preservatives for, paints (in can), coatings, textiles (such as those used in human bedding, footwear, clothing/apparel, upholstery, diapers and carpet), sails, ropes, fire hose, concrete additive, roofing materials, filter media and polyurethane foam and cellulose products and cleaning buffers. The chemical is also formulated to provide residual fungistatic activity in household and domestic dwellings on hard non-porous surfaces, bathroom premises (hard non-porous surfaces), and in garbage cans.

The Environmental Protection Agency has concluded that the FQPA Safety Factor for the trimethoxysilyl quats should be reduced to 3X based on: (1) the potential for significant contact of infants and children through the proposed homeowner uses for this active ingredient and (2) no evidence of increased susceptibility in the prenatal developmental study in rats nor is there evidence of neurotoxicity to the offspring.

Risks summarized in this document are those that result from the use of the active ingredients octadecanaminum-N-N-dimethyl(3-trimethoxysilyl)propyl chloride; octadecanaminum-N-N dimethyl(3 trihydroxy silyl)propyl chloride; tetradecanaminum-N-N dimethyl (3trimethoxysilyl)propyl chloride; and didecyl N-methyl(3trimethoxysilyl)propanaminum chloride. The chemicals have been grouped as trimethoxysilyl quaternary ammonium compounds for the purpose of reregistration.

CHEMICAL OVERVIEW

A. Regulatory History

The trimethoxysilyl quats are registered as active ingredients as bacteriastatic, algaestatic and fungistatic compounds. The first products containing a trimethoxysilyl quat were registered in January 1960. There are currently a total of 30 registered products for PC Codes107401, 169160, 107403 and 107409. The Agency has determined that the Reregistration Eligibility Decision (RED) will include all of the aforementioned products, which includes a trihydroxysilyl quat (107403). This decision is supported by the finding that when the methoxysilyl quat compounds are exposed to water, there is a reaction which leads to the formation of hydroxysilyl quat compounds.

Trimethoxysilyl quat and trihydroxysilyl quat containing products are currently used as a material preservative treatment for materials such as those used in human clothing and bedding, carpets and upholstery. The trimethoxysilyl quats are used as surface treatments in household areas and bathroom areas. These products are also used in the manufacturing of paints, coatings, and in concrete. There are no inert uses or tolerances for this reregistration case.

Chemical Identification:

Table 1 contains information on the chemicals included in this RED.

Table 1: Physical and Chemical Properties Chemical name	**1-Octadecanaminium-N,N-dimethyl-N-{3-(trimethoxysilyl)propyl} chloride**	**1-tetradecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl) chloride**	**1-Decanaminium,N-Didecyl-N-methyl-N-{3-(trimethoxysilyl)propyl) chloride**	**1-ocatdecananminium-N,N-dimethyl-N-(3-(trihydroxysilyl)propyl)-chloride**
Empirical Formula	$C_{26}H_{58}ClNO_3Si$	$C_{22}H_{50}ClNO_3Si$	$C_{27}H_{60}ClNO_3Si$	$C_{23}H_{52}ClNO_3Si$
CAS #	27668-52-6	41591-87-1	6895920-6	199111-50-7
OPP Chemical Code	107401	107409	169160	107403
Molecular Weight	496.30	440.31	510.3	454
Physical State	liquid	liquid	liquid	liquid
Color	Pale yellow to off white	Clear yellowish	Light to dark amber	clear
Melting Point	267 C	245 C	272 C	306 C
Boiling Point	617 C	570 C	628 C	702 C
Specific Gravity	0.99	1.012	0.85	1.0
Vapor Pressure	5.8×10^{-14} mm Hg	1.7×10^{-12}	2.4×10^{-14}	1.85×10^{-21}

Basic Manufacturers: Aegis Environmental Mgt, Inc., Sishield Technologies, Inc.

Use Profile

The following section provides information on the currently registered uses of the trimethoxysilyl quat products. Included is an overview of the use sites and application methods for these compounds. Please refer to appendix A for a comprehensive table of uses of the trimethoxysilyl quats that are eligible for reregistration.

Type of Pesticide: Material preservatives, bacteriastatic, fungistatic, antimicrobial and algaestatic treatments
Use Sites: Trimethoxysilyl quats are used in industrial, commercial, institutional and residential premises.
Use Classification: Trimethoxysilyl quats are general use pesticides.

Formulation Types: Trimethoxysilyl quats are formulated as a soluble concentrate for both manufacturing and end use products and as a ready to use solution for end use products.
Application Rates/ Methods: As a materials preservative and surface treatment, trimethoxysilyl quats are applied by open pour methods or by spraying, dipping or soaking, depending upon the material that is being treated. The application rates vary based on product and use site. A complete list can be found as part of Appendix A.
Type of Pesticide: Material preservatives, bacteriastatic, fungistatic, antimicrobial and algaestatic treatments

Human Health Risk Assessment

Toxicity of Trimethoxysilyl Quats

A brief overview of the toxicity of the trimethoxysilyl quats is presented below. Further information on the toxicity of this compound can be found in Appendix C in a risk characterization document dated February 2, 2000.

The Agency has reviewed all toxicity studies submitted for the trimethoxysilyl quats and has determined that the toxicological database is sufficient for reregistration. The toxicological database for trimethoxysilyl quats is currently comprised of unpublished studies submitted to the Agency; however, limited data are available for these compounds. The data matrix for trimethoxysilyl quats includes acute toxicity studies, a subchronic dermal toxicity study, one subchronic oral study in rats, one developmental toxicity study in rats, and six mutagenicity studies (four of which have been classified as being acceptable).

Table 2. Toxicity of Trimethoxysilyl Quats Test	Species	Results	MRID
Oral LD_{50}	Rat	>5000 mg/kg (Toxicity Category IV)	40385201
Dermal LD_{50}	Rabbit	>2000 mg/kg (Toxicity Category III)	40385201
Inhalation LC_{50}	Rat	>2.0 mg/L (1-Hour) (Toxicity Category IV)	Not available*
Eye Irritation	Rat	Severe Ocular Toxicity (Toxicity Category I)	403385201
Dermal Irritation	Rabbit	Severe dermal toxicity (Toxicity Category I)	Not available*
Subchronic dermal toxicity	Rat	Dermal and Systemic NOAEL > 1000 mg/kg/day	41339403
Subchronic oral toxicity	Rat	NOAEL > 240 mg/kg/d (HDT)	46280411
Developmental Toxicity	Rat	Maternal NOAEL > 1000 mg/kg/day Developmental NOAEL > 1000 mg/kg/day	41438003
Ames Salmonella Assay	Salmonella	No increase in number of revertant colonies (unacceptable study)	40385211
In-vitro Reverse Mutation Assay	Salmonella, E-coli	No evidence of induced mutant colonies	46280412
In-vitro Forward Mutation Assay	Salmonella, E-coli	No evidence of mutagenicity	46280413
Chromosome Aberration	Chinese hamster cells	No association with the induction of structural chromosome aberrations	46280414
Mouse Micronucleus	Mouse	No evidence of compound induced cytotoxicity	41296803
Unscheduled DNA Synthesis	Hepatocytes	Unacceptable study	41296804

* These studies are summarized in the data base for the trimethoxysilyl quats, however, accession/MRID numbers were not included on the study reviews.

General Toxicity Observations

Upon reviewing the available toxicity information, the Agency has concluded that there are no endpoints of concern for repeated oral or dermal exposure to the trimethoxysilyl quats. This conclusion is based on low toxicity observed in acute, subchronic and developmental studies conducted with the trimethoxysilyl quat compounds. The risk from inhalation exposure has not been characterized and an additional study designed to assess inhalation toxicity over time may be needed. In addition, severe toxicity has been observed with regard to skin and eye irritation.

Carcinogenicity Classification

There are no concerns for carcinogenicity for the trimethoxysilyl quats based on the results of the mutagenicity studies and the lack of any systemic toxicity being observed in the toxicity data base; therefore, no carcinogenic analysis is required.

Mutagenicity Potential

The mutagenicity of the trimethoxysilyl quats is fully characterized. For all of the compounds covered under this RED, there are a total of four acceptable mutagenicity studies, all of which demonstrate that the trimethoxysilyl quats are negative for mutagenicity.

FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X) to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, residential exposures, or to compensate for an incomplete database. The FQPA Safety Factor has been reduced to 3X based on: (1) the potential for significant contact of infants and children through the proposed homeowner uses for this active ingredient and (2) no evidence of increased susceptibility in the prenatal developmental study in rats nor is there evidence of neurotoxicity to the offspring. It should be pointed out that at this time, there are no risks of concern which would require the use of a FQPA safety factor.

Population Adjusted Dose (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern. Since toxicological endpoints for the risk assessment were not identified based on the available data, RfDs and PADs have not been calculated for trimethoxysilyl quats. In addition there does not appear to be oral exposure to this chemical based on use patterns.

Dietary and Residential Risk Assessment

There are currently no dietary exposure scenarios for the trimethoxysilyl quats. Although there are residential uses for trimethoxysilyl compounds, there are no toxicological endpoints of concern based on the available toxicity data.

Aggregate Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information"(FFDCA, Section 408(b)(2)(A)(ii)). Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide and other non-occupational sources of exposure. Residential exposure to the trimethoxysilyl quats is likely; however there are no toxicological endpoints of concern. An aggregate risk assessment was therefore not conducted for this chemical.

Occupational Exposure

The occupational exposure assessment for the trimethoxysilyl quats addresses potential exposures and risks to humans who may be exposed in "occupational settings." An occupational risk assessment is required for an active ingredient if certain toxicological criteria are triggered and there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For the trimethoxysilyl quats there is potential for exposure; however, there are no toxicological endpoints of concern according to a review of the available toxicity data.

Human Incident Data

EPA consulted the following sources of information for human poisoning incidents related to the trimethoxysilyl quats: (1) OPP Incident Data System (IDS), (2) California Department of Pesticide Regulation (1982-2004) and (3) National Pesticide Information Center (NPIC). There were no human incidents reported for the trimethoxysilyl quats in these data bases.

Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is based on the use sites for the trimethoxysilyl quats and any associated uncertainties. For further information concerning all aspects about the environmental risk assessment refer to the product chemistry, environmental fate and ecological toxicology in the trimethoxysilyl quats risk assessment available on the Agency's website in the EPA Docket at http://www.regulations.gov.

Environmental Fate and Transport

The Agency has conducted an environmental fate assessment dated September 19, 2007 for the trimethoxysilyl quats. The hydrolysis data indicate that the trimethoxysilyl quats are soluble but not stable in water. Environmental fate studies for the trimethoxysilyl quats consist of only a hydrolysis study and it was concluded by the Agency that no further fate studies would be required because of the instability of the compounds and the formation of an insoluble silane degradate. The trimethoxysilyl quats are not expected to contaminate surface or ground water due to rapid degradation by hydrolysis.

Ecological Risk

The Agency expects exposure to the trimethoxysilyl quats to be minimal to avian, fresh water estuarine/marine aquatic organisms and plants based on the registered indoor use patterns.

Toxicity (Hazard) Assessment

The results from the avian acute toxicity and dietary studies and from the freshwater invertebrate acute toxicity studies for the trimethoxysilyl quats are summarized in Table 3. The trimethoxysilyl quats are characterized as practically non-toxic to birds and based on the data in the

Agency's files, the chemical is considered highly toxic to freshwater invertebrates in acute studies. The trimethoxysilyl quats are classified as being moderately toxic to coldwater fish species.

Table 3: Ecological Acute Toxicity Studies

Table 3: Ecological Acute Toxicity Studies Test and Organism	**Chemical PC Code**	**Results**	**Toxicity Category**
Acute Toxicity LC_{50} Rainbow Trout	169160	96 hour LC_{50} = 1.73 mg/L	Moderately toxic
Single Dose Oral LD_{50} Mallard Duck	107401	LD_{50} > 1590 mg/kg	Practically non-toxic
Dietary LC_{50} Mallard Duck	107401	LC_{50} > 5620 mg/L	Practically Non-toxic
Eight –day Dietary LC_{50} Bobwhite Quail	169160	LC_{50} > 5620 mg/L	Practically Non-toxic
Acute Toxicity LC_{50} Freshwater Daphnids	169160	LC_{50}=0.18mg/L	Highly toxic

Risk to Threatened and Endangered Species

It is expected that the proposed uses for the trimethoxysilyl quats will involve minimal environmental exposure from registered use patterns. However, an endangered species effect determination has not been made at this time because a more refined assessment that would include direct, indirect and haThe Agency has completed its assessment of the dietary, occupational and ecological risks associated with the use of pesticide products containing trimethoxysilyl quats as the active ingredient. Based on a review of the data and other available information for the active ingredient, the Agency has concluded that there is sufficient information on the human health and ecological effects of the trimethoxysilyl quats to make decisions as part of the reregistration process under FIFRA, as amended by FQPA. The Agency has determined that products containing trimethoxysilyl quats are eligible for reregistration provided that current data gaps and confirmatory data needs are addressed. Appendix A summarizes the uses of the trimethoxysilyl quats that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of the trimethoxysilyl quats and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on the evaluation of the trimethoxysilyl quats, the Agency has determined there are no human health or ecological risks of concern.

Food Quality Protection Act Findings

An FQPA Safety Factor of 3X was recommended for the trimethoxysilyl quat compounds. Although there are no food uses for these compounds, it is likely that infants and children will be exposed to these compounds through the existing uses. The FQPA Safety Factor was reduced to 3X, based on the findings that there was no evidence of increased susceptibility in the prenatal

developmental study in rats and there was no evidence of neurotoxicity to the offspring. There is a lack of a second developmental toxicity study in a second species for this acticle

Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the use of the trimethoxysilyl quats as an active ingredient. The Agency believes there is reasonable certainty of no harm resulting from exposure to the trimethoxysilyl quats as an active ingredient to the general population and to infants and children in particular. This is based on the existing toxicity datawhich supports the finding that these products did not elicit a toxic response when administered to laboratory animals at the limit dose level. In addition, in conducting a human health hazard assessment, the Agency found that there were no endpoints of concern for the oral and dermal routes of exposure.

The Agency believes that the trimethoxysilyl quats have minimal potential to cause human health or environmental risks and has determined that a qualitative approach to assessing human health and ecological risks from exposure to the trimethoxysilyl quats is appropriate. Therefore, no risk mitigation measures are necessary at this time. ve ingredient and a lack of a two-generation reproduction study.

END OF DOCUMENT

TEXAS DEPARTMENT OF AGRICULTURE
COMMISSIONER SID MILLER

June 5, 2020

Mr. Adam Zerrenner
Assistant Field Supervisor
U.S. Fish and Wildlife Service
Hartland Bank Building
10711 Burnet Road, Ste.200
Austin, Texas 78758

Dear Mr. Zerrenner:

This is to advise your agency that the Texas Department of Agriculture (TDA) has submitted an application to the U. S. Environmental Protection Agency (EPA) for a Public Health emergency exemption to authorize the use of *Dimethyl octadecyl 3-(trimethoxysilyl) propyl ammonium chloride* (SurfaceWise™ 2 , EPA Reg. No. unregistered) to reduce the spread of COVID-19 by controlling the SARS-CoV-2 virus on surfaces in Total Orthopedics Spine & Sports (TOSS) facilities in Texas. This action is pursuant to the authority of FIFRA Section 18. The TOSS facility locations and a draft copy of the proposed Section 18 Use Directions are included for your reference.

Section 166.20(a)(8) of Title 40, Code of Federal Registration requires that your agency be notified of this action. Any comments your agency may have relative to the application noted above should be sent to my attention: Kevin.Haack@TexasAgriculture.gov (512) 463-6982.

Sincerely,

Kevin Haack
Coordinator for Pesticide Product Evaluation and Registration

Enclosure:
Proposed Section 18 Use Directions
Total Orthopedics Spine & Sport facility locations

TEXAS DEPARTMENT OF AGRICULTURE
COMMISSIONER SID MILLER

June 5, 2020

Dr. Jong Song Lee
MC 168, Toxicology
Texas Commission on Environmental Quality
P.O. Box 13087
Austin, TX 78711-3087

Dear Dr. Lee:

This is to advise your agency that the Texas Department of Agriculture (TDA) has submitted an application to the U. S. Environmental Protection Agency (EPA) for a Public Health emergency exemption to authorize the use of *Dimethyl octadecyl 3-(trimethoxysilyl) propyl ammonium chloride* (SurfaceWise™ 2 , EPA Reg. No. unregistered) to reduce the spread of COVID-19 by controlling the SARS-CoV-2 virus on surfaces in Total Orthopedics Spine & Sports (TOSS) facilities in Texas. This action is pursuant to the authority of FIFRA Section 18. The TOSS facility locations and a draft copy of the proposed Section 18 Use Directions are included for your reference.

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Sincerely,

Kevin Haack
Coordinator for Pesticide Product Evaluation and Registration

Enclosure:
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TEXAS DEPARTMENT OF AGRICULTURE
COMMISSIONER SID MILLER

June 5, 2020

Mr. Al Cherepon
Water Planning & Assessment
Texas Commission on Environmental Quality
P.O. Box 13087
Austin, TX 78711-3087

Dear Mr. Cherepon:

This is to advise your agency that the Texas Department of Agriculture (TDA) has submitted an application to the U. S. Environmental Protection Agency (EPA) for a Public Health emergency exemption to authorize the use of *Dimethyl octadecyl 3-(trimethoxysilyl) propyl ammonium chloride* (SurfaceWise™ 2 , EPA Reg. No. unregistered) to reduce the spread of COVID-19 by controlling the SARS-CoV-2 virus on surfaces in Total Orthopedics Spine & Sports (TOSS) facilities in Texas. This action is pursuant to the authority of FIFRA Section 18. The TOSS facility locations and a draft copy of the proposed Section 18 Use Directions are included for your reference.

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Sincerely,

Kevin Haack
Coordinator for Pesticide Product Evaluation and Registration

Enclosures:
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TEXAS DEPARTMENT OF AGRICULTURE
COMMISSIONER SID MILLER

June 5, 2020

Ms. Kathy Boydston
Wildlife Division - Habitat Assessment
Texas Parks & Wildlife Department
4200 Smith School Road
Austin, TX 78744

Dear Ms. Boydston:

This is to advise your agency that the Texas Department of Agriculture (TDA) has submitted an application to the U. S. Environmental Protection Agency (EPA) for a Public Health emergency exemption to authorize the use of *Dimethyl octadecyl 3-(trimethoxysilyl) propyl ammonium chloride* (SurfaceWise™ 2 , EPA Reg. No. unregistered) to reduce the spread of COVID-19 by controlling the SARS-CoV-2 virus on surfaces in Total Orthopedics Spine & Sports (TOSS) facilities in Texas. This action is pursuant to the authority of FIFRA Section 18. The TOSS facility locations and a draft copy of the proposed Section 18 Use Directions are included for your reference.

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Sincerely,

Kevin Haack
Coordinator for Pesticide Product Evaluation and Registration

Enclosure:
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