



An Introduction to SIQURA

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COVID-19 Comment

The SIQURA Hand and Surface antimicrobial chemistry utilises a combination of proven Quaternary Ammonium Compounds (QAC's) combined with our unique surface bound antimicrobial to provide not only disinfection of surfaces but also ongoing protection for surfaces against pathogenetic microbes.

- The US EPA has provided a list of disinfectant agents that are seen to be effective against Viruses including Corona Viruses. This list includes the QAC's found in SIQURA products
- (<https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>)
- The Canadian Governments has provided a list of Hand Sanitisers that are effective against Corona Virus. This list includes This list includes the QAC's found in SIQURA products (Please visit <https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19/hand-sanitizer.html#tbl1>)
- The Australian Health department has provided guidance on disinfectants that are effective against Corona Viruses This list includes the QAC's found in SIQURA products
- The Singapore Government has listed the QAC's found in SIQURA products as being effective against Covid 19
- The WHO has listed the QAC's found in SIQURA products as a recommended disinfectant for Lab Biosafety when dealing with Covid-19
- The Australia TGA has also approved disinfectants that utilise the QAC's found in SIQURA products s as being effective against Corona virus.

In this current environment it is important to understand that SIQURA products contain antimicrobial agents that have proven antimicrobial efficacy and are, at time of writing undergoing testing and review for inclusion on regulatory listings. Given the enormous strain being placed on testing and regulatory bodies, our official registration documentation is taking longer than anticipated. However, given the large amount of research and data available it is reassuring to know that SIQURA chemistry has been tested and found to be effective against pathogenic microbes many times over. Please refer to the attached test reports for efficacy testing. At present SIQURA do not make more direct regulatory claims regarding COVID-19 . Formal regulatory statements will be made as soon as the official documentation comes to hand.

Anti-Viral claims are pending TGA testing which has been delayed due to the current COVID-19 backlog – We should see results soon, estimated around mid-May to early June.

Until SIQURA receive approval this product is ONLY recommended for general and industrial workplaces and homes to Kill 99.99% of germs & microbes.

SIQURA understands that there may be may other companies making misleading or fraudulent claims regarding efficacy against Covid-19. We have seen many recent media articles pointing to product recalls and fines incurred by companies making such claims.

SIQURA will not make any claim that cannot be backed up by testing and regulatory approvals, but we can currently state "That many Health Departments recommend these active ingredients in the fight against coronavirus and according to the US EPA, The Canadian Government, The Singapore Government, The W.H.O and Local Australian governments and agencies, the active ingredients in our products are listed as being effective against the Human coronavirus (Strain 229E of HCoV).

Textile treatments are not governed by the TGA. The chemistry of SIQURA and Siquira has been tested against Feline Corona Virus (Accepted Covid-19 Surrogate) on an applied textile substrate. Further testing in underway to determine the effectiveness of Siquira against COVID-19. This testing forms part of a study being conducted by Queensland University to assist with the manufacture of PPE for Australian Health Care workers.

INTRODUCTION

Almost all materials have one thing in common; they face a common enemy. Bacteria, fungi, algae, and other organisms can consume and degrade surfaces during shipment, storage, and use, causing loss of product as well as exposing the manufacturer to potential liability. Contamination and colonization of microorganisms on surfaces can result in problems as small as an offensive odor to serious human infections and death. Imparting an antimicrobial agent into synthetic material can create microbial resistant, non-porous surfaces that can alleviate many of these problems. However, selecting the right antimicrobial is essential to provide the appropriate protection to the product as well as to protect our environment. The list of available agents becomes limited when the criteria selection includes durability, regulatory approvals (EU BPR, USEPA), spectrum of activity, and toxicity to both the manufacturer and the end-user.

The use of Siquira antimicrobial agents can provide durable antimicrobial protection against a wide variety of microorganisms without the worry of leaching heavy metals, phenolic compounds or other toxic compounds that continue to contaminate our environment and present situations that promote microbial resistance.

Altering surfaces with durable non-leaching antimicrobial agents such that they provide an active killing "field" for killing one-celled organisms on contact is very desirable. The use of the Siquira antimicrobial has been demonstrated to provide such treatments on a wide variety of surfaces and end-use conditions. Siquira antimicrobial agents can both self crosslink and can link with available surface sites to create fully cured polymer that binds directly to the surface providing an antimicrobial coating that becomes part of the substrate itself. The non-leaching behavior of such a reactive surface allows for the control of surface microbial contamination without the continuous release of toxic components into the environment, which can promote the formation of resistant organisms.

MICROORGANISMS

Mould, mildew, fungus, yeast, bacteria, and virus (microorganisms), are part of our everyday lives. There are both good and bad types of microorganisms. The thousands of species of microorganisms that exist are found everywhere in the environment, on our garments, on our bodies and on virtually every surface around us. Microorganisms, their body parts, metabolic products, and reproductive parts, cause multiple problems to synthetic materials. They are human irritants, sensitizers, toxic-response agents, causers of disease, and simple discomforting agents. Clearly, microorganisms are the most potent pollutants in our environment, on our clothes, and on our furnishings.

Microorganisms need moisture, appropriate temperatures, nutrients, and most of them need to be associated with a surface. Textiles, apparel, bathrooms, carpets, draperies, wall coverings, furniture, bedding and ceiling tiles create ideal habitats for microorganisms due to the high levels of humidity seen in these environments during common use. Nutrients utilized by microorganisms can be organic material, inorganic material, and/or living tissue. For example, bacteria play an important role as part of the body's micro flora, and along with the skin, are shed continuously.

Given acceptable growth conditions, they can multiply from one organism to more than one billion in just 18 hours. Over time, microorganisms can form highly complicated and durable microbial colonies that attach themselves to surfaces. These microbial biofilms are a prime concern in the medical industry and must be controlled before they form on the surface themselves.

Microorganisms cause problems with raw materials and processing chemicals, wet processes in mills, roll or bulk goods in storage, finished goods in storage and transport, and goods as the consumer uses them. They are also an annoyance and aesthetic problem to architects, builders, and homeowners. The economic impact of microbial contamination is significant and the consumer interests and demands for protection are at an all time high.

ANTIMICROBIALS

The term antimicrobial refers to a broad range of technologies that provide varying degrees of protection for both organic and synthetic products against microorganisms. Antimicrobials are very different in their chemical nature, mode of action, impact on people and the environment, implant-handling characteristics, durability on various substrates, costs, and how they interact with good and bad microorganisms. Antimicrobials are used in and on a variety of substrates to control bacteria, fungi, and algae. This control reduces or eliminates the problems of deterioration, staining, odors, and health concerns that they cause. Additionally, antimicrobial agents may prevent the loss of product during transport and can potentially reduce legal liability when microbial contamination occurs.

In the broad array of microorganisms there are certainly both good and bad types. Antimicrobial strategies for bad organisms must include ensuring that non-target organisms are not affected or that adaptation of microorganisms is not encouraged. For instance, antimicrobial agents applied to textiles must control all microorganisms on the textile without leaching into the environment and affecting the natural biological skin flora. In addition, as sub lethal doses of antimicrobial agents may lead to adaptation. The antimicrobial agent should not lose effectiveness over time and cannot diminish in effective concentration.

Antimicrobial agents can be classified in two main types, leaching and non-leaching.

- Leaching antimicrobial agents are defined as agents that must come off the treated substrate in order to exert the antimicrobial properties. Any antimicrobial agent that must enter the cell to work is considered a leaching agent.
- Non-leaching agents are fixed to the treated surface and subsequently do not need to leave this surface to provide antimicrobial action. As these agents are physically attached, there is generally no means for removal and therefore no means to diminish the overall strength.

The need for new and safer antimicrobial technologies is obvious. These new agents must be safer to the end-use, the applicator, and also to the earth. Antimicrobial agents that do not leach from the original treatment site can provide for this protection.

But even non-leaching is not enough. Antimicrobial agents in general must have broad spectrum antimicrobial activity (equally effective against bacteria, fungi, and algae), have little to risk to the product or to the people applying the product, must easily fit current production systems, must be environmentally friendly, and must be compliant with all global biocidal regulations (U.S. EPA, EU BPR, REACH). And as we now enter a period where an alarming amount of bacteria and viruses have become resistant to antibiotics and antimicrobials it is critical to select antimicrobial agent that will not promote microbial resistance.

ORGANOFUNCTIONAL SILANE

In the mid-1960's, researchers discovered that antimicrobial organofunctional silane could be chemically bound to receptive substrates by Si-O linkages. The method orientates the organofunctional silane in such a way that hydrolysable groups on the silicon atom were hydrolyzed to silanols and the silanols formed chemical bonds with each other and the substrate. The resultant surface modification, when an antimicrobial agent such as quaternary nitrogen was included, provided for the antimicrobial to be oriented away from the surface.

The attachment of this chemical to surface involves two processes.

- First and most important is a very rapid process that coats the substrate with the cationic species one molecule deep. This is an ion exchange process by which the cation of the silane quaternary ammonium compound replaces protons from water on the surface. It has long been known that most surfaces in contact with water generate negative electrical charges at the interface between water and the surface
- The second process is unique to materials such as silane quaternary ammonium compounds that have silicon functionality enabling them to polymerize, after they have coated the surface, to become almost irremovable even on surfaces with which they cannot react covalently. Covalent bonding to the surface can also occur and through a series of heating and cooling steps, it is also possible to have intermolecular polymerization creating interpenetrating network in which the reactive silane forms anchors for additional polymer formation. Once hydrolyzed, the silanol groups become functionalized and are able to react with itself and available sites on the surface to form a dense polysiloxane network with an extremely high cationic charge density capable of destroying microbes.

ACTIVE INGREDIENT

The principal active ingredient of Siqura products is 3-(trimethoxy silyl) propyl dimethyl octadecyl ammonium chloride. The structure is shown in Figure 1.

When the compound is exposed to water (in the production process for SIQURA), a trihydroxy silyl quaternary ammonium compound with the chemical structure, $(\text{HO})_3\text{SiCH}_2\text{CH}_2\text{CH}_2\text{N}^+(\text{CH}_3)_2\text{C}_{18}\text{H}_{37}\text{Cl}$ is formed. This resulting silanol exists in stable aqueous solution in the Products.

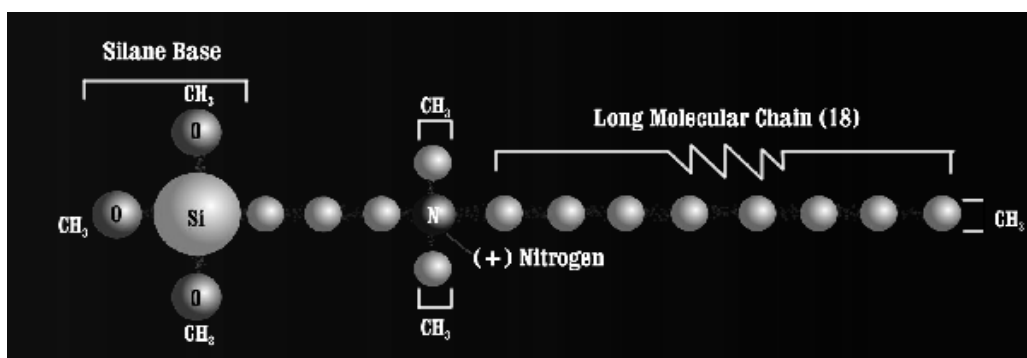


Figure 1: Active Ingredient of SIQURA Surface Sanitiser

Synonyms for the trimethoxy compound include 1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxy silyl)propyl)-, chloride ODTA, 27668-52-6 or 27668526 (CAS Number), 02127 (CA DPR Chem Code), 107401 (US EPA PC Code), 2127 (CA DPR Chem Code), 107401 (OPP Chemical code) and Dow Corning 5700. EC Number 248-595-8. Synonyms for the trihydroxy compound include 199111-50-7 (CAS Number) and 107403 (OPP Chemical Code).

ANTIMICROBIAL ACTIVITY OF THE SIQURA ANTIMICROBIAL

The data represent over 35 years of experience and microbiological and chemical testing measuring the effectiveness of the silane quaternary ammonium antimicrobial agent after being applied onto surfaces such as clothing, furniture, carpets, wood and vinyl flooring, non-woven textiles (air filters), aquariums, etc. Has shown the surfaces be resistant to the formation of biofilm.

The property of the Siqura Antimicrobial that provides for the physical contact and rupturing of the cell membranes of single celled organisms revolves around the chemical structure of the monomer and subsequent final polymer. Contact with the oleophilic parts of the long carbon chain and high cationic charge density exerted by the quaternized nitrogen of the polymer by the cell membranes of single celled organisms causes the physical rupture and inactivation of the membrane and the inhibition and death of the microbe. This active ingredient monomer, when applied to surfaces and polymerized, provides a mode of antimicrobial activity that physically ruptures the cell membranes of microorganisms by ionic association (cell membranes carry a negative charge) and lipophilic attraction (the C18 associating with the lipoprotein of the membrane) causing disruption and lyses of the microbial cell.

CONTROLLING BIOFILM DEVELOPMENT

Microbial contamination and subsequent biofilm formation is a major cause of infection, contamination, and product deterioration. Controlling or even removing the biofilm after its development is difficult. A useful strategy is to control biofilm formation before it starts. For the prevention of biofilm formation, control of both adherence and colonization of the microorganisms on the substrate surface is critical. One of the strategies to prevent biofilm formation is to modify the physiochemical properties of a surface in order to minimize or reduce the attraction of the surface to the microorganism thereby controlling adherence. Reducing the attraction simplistically can be done either by manipulating the ionic charge of the surface altering the electrostatic interface or changing the hydrophobic/hydrophilic properties through surface energy manipulations (or both)

Controlling or minimizing the adhesion of microorganisms to the surface can be done using several techniques. Strategies used in the modification of surface characteristics range from altering the physical properties of the surface via mechanical abrasion to covalently attaching functional components to the surface. However, controlling the physical surface properties through water repellency does not appear to be enough to prevent biofilm formation. Bacteria can still adhere to highly hydrophobic surfaces.

Creating an active antimicrobial surface through the use of Siqura Antimicrobial will destroy the adhering microorganisms, single celled organisms, thereby preventing further proliferation.

It is critical, of course, that to use an antimicrobial agent in the prevention of biofilm formation, the agent must be broad spectrum and active against the particular biofilm causing organisms. The Siqura Antimicrobial technology is specific against all tested organisms typically responsible for biofilm formation.

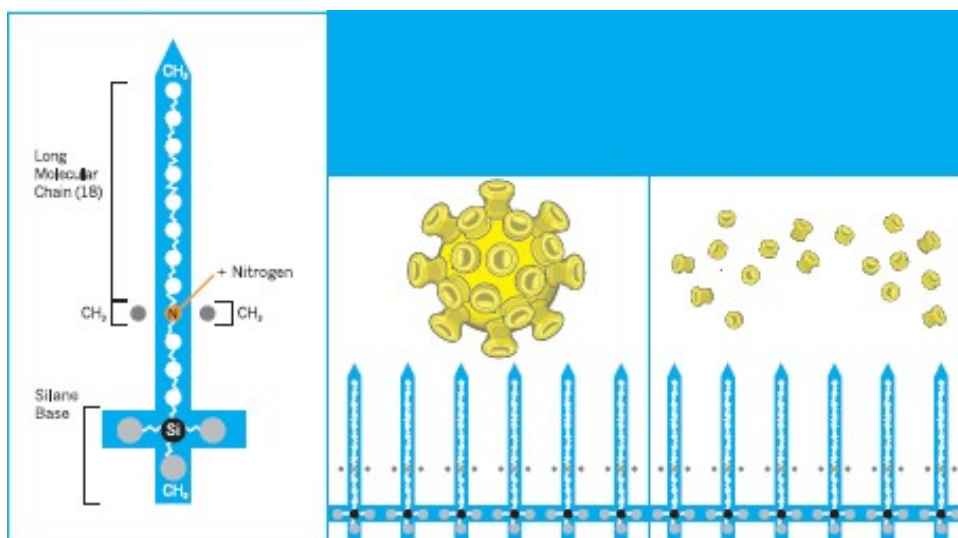
The Siqura Antimicrobial technology when applied to surfaces affects both the adhesion properties of microorganisms due to increased hydrophobic properties of the long carbon chain fully polymerized and also directly destroys one celled organism on contact through mechanisms described above

Bonding to a surface and drying is a key element of the effectiveness of this technology. Speier and Malek reported in 1982 that the amount of substance needed to kill E. coli having been deposited on a solid surface was insufficient to have the same effect in solution. Using scanning electron photomicrography, these authors showed that E coli and S.aureus were destroyed within 30 minutes on treated fabric apparently by rupture of their cell walls. Furthermore, the activity of the treated surface was retained after washing (Speier and Malek 1982).

When SIQURA is applied to surfaces including human skin and allowed to dry the hydroxyl group on the silane base bonds to the surface. The other hydroxyl groups at the silane base also cross-link by condensation

type reactions with other molecules. A stable protective layer of molecules forms with the long molecular chains protruding from the surface / skin's surface. The nitrogen molecule confers a positive charge, which attracts microorganisms to the layer. These microorganisms are then killed by cell destruction on the long molecular chains as shown in Figure 2 below.

Figure 2: Mode of Action of Active Ingredient



As can be seen from the mechanism of action, Siqura products kill microorganisms mechanically and therefore resistance does not develop.

RATIONALE FOR THE APPLICATION OF SURFACE DISINFECTION AND PROTECTION

Using proper surface disinfection can prevent infection both in the health care setting as well as in industrial environments. When selecting a surface disinfectant, various features characterize currently available disinfectants used on environmental surfaces such as rapid action, spectrum of activity (such as bactericidal, sporicidal, fungicidal and virucidal activity), efficacy in the presence of protein or blood, toxicity, user safety, and material compatibility. Broadly, current disinfectants include alcohol-based disinfectants, chlorine-based disinfectants, quaternary ammonium compounds, hydrogen peroxide and phenol-based products.

Drawbacks of current disinfectants for surfaces in particular include toxicity and safety for users and corrosive action on surfaces being disinfected e.g. latex gloves, textiles and metallic surfaces. Another drawback of current disinfectants is the duration of activity. Although many are effective biocidal agents, their action has limited longevity and they do not provide long lasting protection against re-colonization of surfaces by microorganisms.

SIQURA addresses some of the issues associated with current disinfectants in that it remains active on a wide range of surfaces long term, has a broad spectrum of action, is safe for users and is compatible with many materials which would otherwise be damaged by chemical disinfectants. Furthermore, it is safe for humans, animals and plants and does not discolor, stain or corrode surfaces on which it is applied. It has a broad spectrum of activity and can be used in conjunction with other biocidal agents.

RATIONALE FOR THE USE OF HAND SANITIZERS

For many years, hand washing with soap and water has been considered a measure of personal hygiene. In the last 200 years, it has been understood that diseases, caused by infectious agents are transmitted via the hands of health care workers. In the community, hand hygiene has been acknowledged as an important measure to prevent and control infectious disease and to significantly reduce the burden of infectious disease. Currently, hand hygiene is considered the most important measure for preventing the spread of pathogens and preventing infectious disease and thereby improving human health (World Health Organization 2009).

In the last two decades guidelines for hand washing alone have evolved to the recommendation that hand sanitizers (such as alcohol based hand rubs) be used in clinical settings especially when health care workers are attending to patients with multidrug-resistant pathogens such as vancomycin-resistant enterococci (VRE) and methicillin-resistant *Staphylococcus aureus* (MRSA).

A systematic review of publications between 1992 and 2002 with an adequate methodological quality on the effectiveness of alcohol-based solutions for hand hygiene showed that alcohol-based hand rubs remove organisms more effectively, require less time and irritate skin less often than hand washing with soap or other antiseptic agents and water (Picheansathian 2004).

With the recent H1N1 (swine flu) pandemic and current COVID-19 pandemic, there has been a greater emphasis on the prevention of spread of infectious disease by implementing good standards of hand hygiene. This has included public health campaigns on hand washing as well as the more widespread availability, sales and use of hand sanitizers. This use of hand sanitizers in everyday life has been advocated to improve general hand hygiene and reduce the spread of infectious disease in the community (such as schools, offices, households) as well as in health care settings.

Most hand sanitizers use alcohol solutions to reduce the number of pathogens on the hands and therefore minimize their spread from one person to another. The antimicrobial activity of alcohols results from their ability to denature proteins. Alcohol solutions containing 60 to 80% alcohol are most effective, with higher concentrations being less potent. This paradox results from the fact that proteins are not denatured easily in the absence of water. Alcohols have excellent in vitro germicidal activity against Gram-positive and Gram-negative vegetative bacteria (including multidrug-resistant pathogens such as MRSA and VRE), *M. tuberculosis*, and a variety of fungi. However, they have virtually no activity against bacterial spores or

protozoan oocysts, and very poor activity against some non-enveloped (non-lipophilic) viruses (World Health Organization 2009).

The efficacy of alcohol-based hand hygiene products is affected by a number of factors, including the type of alcohol used, the concentration of alcohol, the contact time, the volume of alcohol used, and whether the hands are wet when the alcohol is applied. Small volumes (0.2–0.5 ml) of alcohol applied to the hands are not more effective than washing hands with plain soap and water. Larson and colleagues (2010) documented that 1 ml of alcohol was significantly less effective than 3 ml.

Alcohol-based hand rubs are available as solutions, gels and foams. Few data are available regarding the relative efficacy of various formulations, but it is generally accepted that solutions are more effective than gels. Recent studies found similar results demonstrating that solutions reduced bacterial counts on the hands to a greater extent than the tested gels.

Alcohols are flammable; therefore, safety standards apply. Alcohols are also volatile, and containers need to be designed so that evaporation is minimized, and initial concentration is preserved.

Although alcohols are rapidly germicidal when applied to the skin, but they do not have persistent activity. Therefore, to be continuously effective the products need to be re-applied on a regular basis. Frequent use of alcohol-based formulations for hand antisepsis tends to cause drying of the skin unless humectants or other skin conditioning agents are added to the formulations.

Compliance is an important issue for both health care workers and others. Products that are pleasant to use and readily available, increase compliance and overall effectiveness of hand hygiene programs. Alcohol based sanitizers dry the skin, which means users may apply them less frequently than recommended.

The key attributes which make SIQURA different from alcohol-based rubs are its effectiveness against a wide range of organisms, its longevity on the hands and its emollient effect which minimizes drying and makes it more pleasant to use and less likely to cause irritation. The latter is expected to improve compliance amongst health care workers and others who need to use such products on a regular basis. SIQURA hand sanitizer can be used in both health care settings and for everyday use to minimize spread of pathogens via contaminated hands.

TEXTILES & CLOTHING

The ideal application for SIQURA (Known as Fresche EF4850 for textiles application) is at point of manufacture where textiles can be treated and the Si-Quat permanently bonded. This provides protection against contamination by bacteria, mould, mildew etc., generally for the life of the garment. In this instance, Siqura is used as a concentrated solution known as Fresche EF4850 in which the textile is steeped before drying. In the industrial setting, technical advisers can check the adherence to the textile using a special reagent to ensure the product has adhered sufficiently to the fabric.

For garments and textiles already in use, Siqura can also be used within the laundry process in order to both eliminate any bacterial contaminants from fabrics including uniforms, lab coats, bedding, sheets, pillows, towels etc., and to also provide an on-going protective barrier against cross contamination. Tests to date confirm that Siqura remains highly effective for up to 100 washes after treatment. Siqura can be used in both warm and cold washes. It is simply used as a substitute for a fabric softener during the rinse cycle. Fabrics can be dried in the normal manner – including the use of a tumble drier. Once dry, the Siqura will have infused into the fabric and will provide an on-going protection.

MICROBIOLOGICAL SPECTRUM OF ACTIVE INGREDIENT

The antimicrobial properties of quaternary ammonium organo silanes against a wide range of pathogens have been described in the literature and include activity against the following:

Table 1: Spectrum of Activity of Active Ingredient

Organism	References
Gram Positive Bacteria	
Bacillus subtilis	(Isquith AJ, 1972)
Micrococcus sp	(Isquith AJ, 1972)
Mycobacterium tuberculosis	(Isquith AJ, 1972)
Propionibacterium acnes	(Isquith AJ, 1972)
Staphylococcus aureus	(Isquith AJ 1972) (Speier and Malek 1982) (Malek, et al., 1981) (Gettings, et al., 1990) (Klein, et al., 1983)
Staphylococcus epidermidis	(Malek and L 1981) (Gettings and White, Skin Treatment Method 1990)
Streptococcus faecalis	(Isquith AJ 1972) (Malek and L 1981) (McGee, Malek and White 1983)
Gram Negative Bacteria	
Aerobacter aerogenes	(Isquith AJ 1972)
Acinetobacter calcoaceticus	(Malek and L 1981) (Gettings and White, Skin Treatment Method 1990)
Enterobacter agglomerans	(Malek and L 1981) (Gettings and White, Skin Treatment Method 1990)
Enterococcus	(Battice and Hales 1986)
Escherichia coli	(Isquith AJ 1972) (Speier and Malek 1982) (Malek and L 1981) (Klein 1983) (Gettings and White 1991) (Battice and Hales 1986) (McGee, Malek and White 1983) (Isquith and CJ 1978) (Abbaszadegan, et al. 2006)
Klebsiella oxytoca	(McGee, Malek and White, New Antimicrobial Treatment for Carpet Applications 1983)
Klebsiella pneumoniae	(Klein 1983) (Gettings and White 1991) (Battice and Hales 1986) (Higgs and White 1994) (Blank, Gettings and White 1989) (McGee, Malek and White 1983) (Blank and White 1992)
Klebsiella terrigena	(Abbaszadegan, et al. 2006)
Proteus mirabilis	(Battice and Hales 1986)
Pseudomonas aeruginosa	(Isquith AJ 1972) (Malek and L 1981) (Klein 1983) (Gettings and White 1991)
Pseudomonas fluorescens	(Battice and Hales 1986)
Salmonella choleraesuis	(Isquith AJ 1972)
Salmonella typhosa	(Isquith AJ 1972)
Bacteriophages	
MS-2	(Abbaszadegan, et al. 2006)
PRD-1	(Abbaszadegan, et al. 2006)
Viruses	
Herpes Simplex Type I	(Tsao and Wang 1990)
Influenza Virus H1N1 strain	(Mikrolab GMBH 2010)
Fungi, Moulds, Yeasts	

Alternaria alternata	(Avery, et al. 1995)
Aspergillus farres	(Isquith AJ 1972)
Aspergillus flavus	(Isquith AJ 1972) (Malek and L 1981)
Aspergillus niger	(Isquith AJ 1972) (Malek and L 1981) (Higgs and White 1994) (Avery, et al. 1995)
Aspergillus terreus	(Isquith AJ 1972)
Aspergillus versicolor	(Malek and L 1981) (Isquith AJ 1972)
Aspergillus verrucaria	(Isquith AJ 1972)
Aureobasidium pullulans	(Avery, et al. 1995)
Candida albicans	(Isquith AJ 1972) (Malek and L 1981)
Cephalascus fragans	(Isquith AJ 1972)
Chaetomium globosum	(Isquith AJ 1972) (Malek and L 1981)
Cladosporium cladosporioides	(Avery, et al. 1995)
Dreschlera australiensis	(Avery, et al. 1995)
Epidermophyton sp.	(Blank, Gettings and White 1989)
Gliomastix cerealis	(Avery, et al. 1995)
Microsporum sp.	(Blank, Gettings and White 1989)
Monilia grisea	(Avery, et al. 1995)
Oscillatoria borneti	(Walters PA 1973)
Penicillium commune	(Avery, et al. 1995)
Penicillium funiculosum	(Isquith AJ 1972) (Malek and L 1981)
Phoma fimeti	(Avery, et al. 1995)
Pithomyces chartarum	(Avery, et al. 1995)
Pullularia pullulans	(Isquith AJ 1972)
Saccharomyces cerevisiae	(Isquith AJ 1972)
Scolecobasidium humicola	(Avery, et al. 1995)
Trichophyton interdigitale	(Isquith AJ 1972) (Malek and L 1981)
Trichophyton madison	(Isquith AJ 1972)
Trichophyton mentogrophytes	(Blank, Gettings and White 1989)
Algae	
Chlorella vulgaris	(Abbaszadegan, et al. 2006)
Cyanophyta oscillatoria	(Isquith AJ 1972)
Cyanophyta anabaena	(Isquith AJ 1972) (Walters PA 1973)
Chrysophyta	(Isquith AJ 1972)
Chrysophyta Selenastrum gracile	(Isquith AJ 1972) (Walters PA 1973)
Chlorophyta Protococcus	(Isquith AJ 1972)
Gonium sp.	(Walters PA 1973)
Pleurococcus sp.	(Walters PA 1973)
Volvox sp.	(Walters PA 1973)
Protozoa	
Cryptosporidium parvum (oocysts)	(Abbaszadegan, et al. 2006)

Note that specific laboratory test results for Products are presented in the Section 4.

TOXICOLOGY OF ACTIVE INGREDIENT

Toxicology of the Trimethoxysilyl Quaternary Ammonium Compounds Risks to human health and the environment from the class of compounds known as the trimethoxysilyl quaternary ammonium compounds and their hydroxyl derivatives was reviewed by the US Environmental Protection Agency in a report published in 2007 (United States Environmental Protection Agency 2007). This report entitled “Reregistration Eligibility Decision for Trimethoxysilyl Quaternary Ammonium Chloride Compounds” provides a comprehensive overview of toxicology of the class of compounds to which products belong. The purposes of this report were:

- To reassess potential risks arising from currently registered uses of this class of compounds in the USA.
- To determine the need for additional data on human health and environmental effects.
- To determine whether they met the “no unreasonable adverse effects” criteria of the FIFRA.

HUMAN HEALTH ASSESSMENT - OVERVIEW

This assessment included acute toxicity, sub chronic dermal toxicity, sub chronic oral toxicity, developmental toxicity and mutagenicity.

GENERAL TOXICITY

The EPA concluded there are no endpoints for concern for repeated oral and dermal exposure. This conclusion was based on low toxicity observed in acute, sub chronic and developmental studies conducted with the trimethoxysilyl quat compounds.

CARCINOGENICITY CLASSIFICATION

There were 4 acceptable mutagenicity studies that demonstrated no potential mutagenic effect. The EPA concluded that there are no concerns for trimethoxy silyl quat compounds based on the results of the mutagenicity studies and the lack of any systemic toxicity being observed in the toxicity database (human incident data), that no carcinogenicity analysis is required. These aspects are summarized in Table 2 below.

Table 2: Toxicology of Active Ingredient

Test	Species	Results
Oral LD50	Rat	>5,000mg/kg (Toxicity Category IV)
Dermal LD50	Rabbit	>2,000mg/kg (Toxicity Category III)
Inhalation LC50	Rat	>2mg/litre (1-hour) (Toxicity Category IV)
Eye Irritation	Rat	Severe Ocular Toxicity (Toxicity Category I)
Dermal Irritation	Rabbit	Severe Dermal Toxicity (Toxicity Category I)
Sub chronic Dermal Toxicity	Rat	Dermal and Systemic NOAEL >1,000mg/kg/day
Sub chronic Oral Toxicity	Rat	NOAEL >240mg/kg/d (HDT)
Developmental Toxicity	Rat	Maternal NOAEL >1,000mg/kg/day Developmental NOAEL >1000mg/kg/day
In vitro Reverse Mutation Assay	Salmonella, E.coli	No evidence of induced mutant colonies
In vitro Forward Mutation Assay	Salmonella, E.coli	No evidence of mutagenicity
Chromosome Aberration	Chinese Hamster cells	No association with the induction of structural chromosome aberrations
Mouse micronucleus	Mouse	No evidence of compound induced cytotoxicity

Abbreviations

LD50 = Median Lethal Dose— a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed.

LC50= Median Lethal Concentration – a statistically derived single dose of a substance that can be expected to cause death in 50% of test animals when administered by the route indicated. It is expressed as a weight of substance per unit weight of animal.

NOAEL=No Observed Adverse Effect Level, HDT = highest dose tested

Source: (United States Environmental Protection Agency, 2007)Table 2, Page 6, excluding unacceptable studies.

The EPA also considered environmental risk in terms of environmental fate and transport and ecological risk; being toxicity studies (including rainbow trout, mallard duck, bobwhite quail and freshwater daphnids) and the risks to threatened and endangered species. Overall, the EPA concluded that there were no human health or ecological risks of concern with this class of compounds.

POTENTIAL TOXICITY OF PRODUCTS

As far as the intended use is concerned, SIQURA ACTIVE is applied to surfaces in a concentration of between 0.45 – 0.70%, therefore, the solutions are highly diluted.

PERCUTANEOUS ABSORPTION – ACTIVE INGREDIENT

As far as potential for percutaneous absorption is concerned, there is thought to be no potential for any acute or sub chronic toxicity due to inadvertent percutaneous absorption of the active ingredient even in the presence of broken skin. The dermal LD50 of >2g/kg in rabbits would translate to >282mL/kilogram of a 0.70% solution in humans.

TOXICITY POTENTIAL FROM ORAL INGESTION

As far as oral ingestion of Products is concerned, in view of the findings of the EPA in relation to the class and the lack of any evidence reported around the product, it may be concluded that there is virtually no acute toxicity risk associated with the active ingredient in the product. For example, the LD50 of >5000mg/kg would translate to a volume of >704mL per kg or greater than 49 liters for a 70 kg individual to be ingested by mouth to reach the minimum LD50.

INHALATION, OCULAR OR DERMAL IRRITATION

In everyday use, there is likewise minimal risk of toxicity due to inhalation of the active ingredient. As far as ocular irritation is concerned, because of the presence of the active ingredient contact with the eyes must be avoided and appropriate first aid measures need to be taken if the product comes in contact with the eyes.

ECOTOXICITY

Once Products are applied and bonds to a surface it does not leach into the environment, therefore is considered environmentally non-toxic. Only water molecules are released as a by-product of the condensation reactions that occur during the bonding process.

SAFE HANDLING AND ENVIRONMENTAL IMPACT

The Safety Data Sheet for Products suggest precautions necessary for handling of the product in bulk quantities (for example at the packaging site or when bulk quantities are being transported).

PRODUCTS MANUFACTURING

Site of Manufacture

SIQURA is manufactured by PACSOURCE PTY LTD.

Manufacture is conducted according to the Good Manufacturing Practice Standard (GMP) in an ISO 9001 certified manufacturing facility

TEST RESULTS

The general testing method (s) for SIQURA is detailed in table. These reports can be supplied on request in part and in full (redactions where necessary).

Pathogen	Product	Test Standard	Duration	Laboratory	Lab Test / Certificate Number
Enterococcus hirae - ATCC 10541	Siqura Hand Sanitiser	EN1276:2009	5 min	Merieux NutriSciences	454111014AZZ
Staphylococcus aureus - ATCC 6538	Siqura Hand Sanitiser	EN1276:2010	5 min	Merieux NutriSciences	454111014AZZ
Escherichia Coli - ATCC 8739	Siqura Hand Sanitiser	EN1276:2011	5 min	Merieux NutriSciences	454111014AZZ
Pseudomonas Aeruginosa - ATCC 15442	Siqura Hand Sanitiser	EN1276:2012	5 min	Merieux NutriSciences	454111014AZZ
Salmonella choleraesuis - ATCC 10708	Siqura Hand Sanitiser	AOAC 991.47	10 min	Merieux NutriSciences	454155096ZZZZ
Pseudomonas Aeruginosa - ATCC 15442	Siqura Hand Sanitiser	AOAC 991.49	10 min	Merieux NutriSciences	454155096ZZZZZZ
Staphylococcus aureus subsp. Aureus Rosenbach - ATCC 33591	Siqura Hand Sanitiser	ASTM 2315	10 min	STS	HC19110345
Vancomycin-Resistant Enterococci (VRE) ATCC 51299	Siqura Hand Sanitiser	ASTM 2315	10 min	STS	HC19110345
Escherichia Coli - ATCC 25922	Siqura Hand Sanitiser	ASTM 2315	10 min	STS	HC19110345
Salmonella typhimurium ATCC 14028	Siqura Hand Sanitiser	ASTM 2315	10 min	STS	HC19110345
Staphylococcus aureus - ATCC 6538	Siqura Hand Sanitiser	ASTM 2315	10 min	STS	HC19110345
Pseudomonas Aeruginosa - ATCC 9027	Siqura Hand Sanitiser	ASTM 2315	10 min	STS	HC19110345
legionella pneumophila ATCC 33152	Siqura Hand Sanitiser	ASTM 2315	10 min	STS	HC19110345
Vibrio parahaemolyticus ATCC 17802	Siqura Hand Sanitiser	ASTM 2315	10 min	STS	HC19110345
Staphylococcus aureus subsp. Aureus Rosenbach - ATCC 33591	Siqura Hand Sanitiser	ASTM 2315	24 h	STS	HC19110937
Vancomycin-Resistant Enterococci (VRE) ATCC 51299	Siqura Hand Sanitiser	ASTM 2315	24 h	STS	HC19110939
Escherichia Coli - ATCC 25922	Siqura Hand Sanitiser	ASTM 2315	24 h	STS	HC19110941
Salmonella typhimurium ATCC 14028	Siqura Hand Sanitiser	ASTM 2315	24 h	STS	HC19110943
Staphylococcus aureus - ATCC 6538	Siqura Hand Sanitiser	ASTM 2315	24 h	STS	HC19110345
Pseudomonas Aeruginosa - ATCC 9027	Siqura Hand Sanitiser	ASTM 2315	24 h	STS	HC19110947
Staphylococcus aureus - ATCC 6538	Siqura 75 HG	EN1276	5 min	Eurofins AMS	1311499GLP
Escherichia Coli - ATCC 10536	Siqura 75 HG	EN1276	5 min	Eurofins AMS	1311499GLP
Pseudomonas Aeruginosa - ATCC 15442	Siqura 75 HG	EN1276	5 min	Eurofins AMS	1311499GLP
Enterococcus hirae - ATCC 10541	Siqura 75 HG	EN1276	5 min	Eurofins AMS	1311499GLP
Staphylococcus aureus - ATCC 6538	Siqura 75 HG	EN 13697 after 7 days	60 min	Eurofins AMS	1315921
Escherichia Coli - ATCC 10536	Siqura 75 HG	EN 13697 after 7 days	60 min	Eurofins AMS	1315921
Pseudomonas Aeruginosa - ATCC 15442	Siqura 75 HG	EN 13697 after 7 days	60 min	Eurofins AMS	1315921
Enterococcus hirae - ATCC 10541	Siqura 75 HG	EN 13697 after 7 days	60 min	Eurofins AMS	1315921
Enterococcus hirae - ATCC 10541	Siqura 75 HG	EN1276:2009	5 min	Merieux NutriSciences	454111014AZZZZ

Staphylococcus aureus - ATCC 6538	Siqura 75 HG	EN1276:2010	5 min	Merieux NutriSciences	454111014AZZZZ
Escherichia Coli - ATCC 8739	Siqura 75 HG	EN1276:2011	5 min	Merieux NutriSciences	454111014AZZZZ
Pseudomonas Aeruginosa - ATCC 15442	Siqura 75 HG	EN1276:2012	5 min	Merieux NutriSciences	454111014AZZZZ
Salmonella choleraesuis - ATCC 10708	Siqura 75 HG	AOAC 991.47	10 min	Merieux NutriSciences	454155096ZZZZZZ
Pseudomonas Aeruginosa - ATCC 15442	Siqura 75 HG	AOAC 991.49	10 min	Merieux NutriSciences	454155096ZZZZZZZZ
Staphylococcus aureus - ATCC 6538	Siqura 75 HG	AOAC 991.48	10 min	Merieux NutriSciences	454188404ZZZ
Corona Virus Hcov-229E	Siqura 75 HG	Tech Std for Disinfection	5 min	CAS	JKK20020049E(r)
Enterococcus hirae - ATCC 10541	Siqura 75 CG	EN1276:2009	5 min	Merieux NutriSciences	454111014AZZZ
Staphylococcus aureus - ATCC 6538	Siqura 75 CG	EN1276:2010	5 min	Merieux NutriSciences	454111014AZZZ
Escherichia Coli - ATCC 8739	Siqura 75 CG	EN1276:2011	5 min	Merieux NutriSciences	454111014AZZZ
Pseudomonas Aeruginosa - ATCC 15442	Siqura 75 CG	EN1276:2012	5 min	Merieux NutriSciences	454111014AZZZ
Salmonella choleraesuis - ATCC 10708	Siqura 75 CG	AOAC 991.47	10 min	Merieux NutriSciences	454155096ZZZZZ
Pseudomonas Aeruginosa - ATCC 15442	Siqura 75 CG	AOAC 991.49	10 min	Merieux NutriSciences	454155096ZZZZZZZ
Staphylococcus aureus - ATCC 6538	Siqura 75 CG	AOAC 991.48	10 min	Merieux NutriSciences	454188404ZZ
Vibrio parahaemolyticus ATCC 17802	Siqura 75 CG	ISO 22196	10 min	STS	HC19120547
Legionella pneumophila ATCC 33152	Siqura 75 CG	ISO 22196	10 min	STC	HC19120546
Feline Corona Virus, Strain Munich	Siqura 75 CG	ISO18184	1 h	MSL	J001354
Staphylococcus aureus subsp. Aureus Rosenbach - ATCC 43300	Siqura 75 CG	ISO 22196	45 days	STC	HC20010549
Vancomycin-Resistant Enterococci (VRE) ATCC 51299	Siqura 75 CG	ISO 22196	45 days	STC	HC20010549
Escherichia Coli - ATCC 25922	Siqura 75 CG	ISO 22196	45 days	STC	HC20010549
Salmonella typhimurium ATCC 14028	Siqura 75 CG	ISO 22196	45 days	STC	HC20010549
Staphylococcus aureus - ATCC 6538	Siqura 75 CG	ISO 22196	45 days	STC	HC20010549
Pseudomonas Aeruginosa - ATCC 9027	Siqura 75 CG	ISO 22196	45 days	STC	HC20010549
Legionella pneumophila ATCC 33152	Siqura 75 CG	ISO 22196	45 days	STC	HC20010549
Vibrio parahaemolyticus ATCC 17802	Siqura 75 CG	ISO 22196	45 days	STC	HC20010549
Escherichia Coli - ATCC 25922	Siqura EF4850	ASTM 2180	24h	Interface	M14-207
Escherichia Coli - ATCC 25922	Siqura EF4850	ASTM E2149	24h	Interface	M14-138
Aspergillus brasiliensis - ATCC 9642	Siqura EF4850	ASTM G21	28d	Interface	M14-190
Penicillium funiculosum - ATCC 11797	Siqura EF4850	ASTM G21	28d	Interface	M14-190
Chaetomium globosum - ATCC 6205	Siqura EF4850	ASTM G21	28d	Interface	M14-190
Trichoderma virens - ATCC 9645	Siqura EF4850	ASTM G21	28d	Interface	M14-190
Aureobasidium pullulans - ATCC 15233	Siqura EF4850	ASTM G21	28d	Interface	M14-190
House Dust Mites	Siqura EF4850	AFNOR G 39-011	6w	T.E.C. Laboratories	1531/0812R

House Dust Mites	Siqura EF4850	AFNOR G 39-011	6w	T.E.C. Laboratories	1531/0812R
Candida albicans ATCC-10231	Siqura EF4850	AATCC 100	24h	Intertek	TWNC00280368
Staphylococcus aureus - ATCC 6538	Siqura EF4850	AATCC 100	24h	Intertek	TWNC00273512
Aspergillus niger - ATCC 6275	Siqura EF4850	AATCC 100	24h	Intertek	TWNC00273514
Staphylococcus aureus - ATCC 6538	Siqura EF4850	ASTM 2722	n/a	Interface	M12-148R2
Aspergillus brasiliens - ATCC 9642	Siqura EF4850	ASTM 2722	n/a	Interface	M12-148R2
Staphylococcus aureus - ATCC 6538	Siqura EF4850	ASTM E2149	1h	Interface	M12-029B
Aspergillus brasiliens - ATCC 9642	Siqura EF4850	ASTM G21	28d	Interface	M11-003
Penicillium funiculosum - ATCC 11797	Siqura EF4850	ASTM G21	28d	Interface	M11-003
Chaetomium globosum - ATCC 6205	Siqura EF4850	ASTM G21	28d	Interface	M11-003
Trichoderma virens - ATCC 9645	Siqura EF4850	ASTM G21	28d	Interface	M11-003
Aureobasidium pullulans - ATCC 15233	Siqura EF4850	ASTM G21	28d	Interface	M11-003
Fungal Inhibition	Siqura EF4850	Ford Motor Company Test	28d	Interface	M12-048ford
Klebsiella pneumoniae - ATCC 4352	Siqura EF4850	ASTM E2149	24h	Interface	TS#52733
Klebsiella pneumoniae - ATCC 4352	Siqura EF4850	ASTM E2149	24h	Interface	M14-003
Staphylococcus aureus - ATCC 6538	Siqura EF4850	ASTM E2149	24h	Interface	M14-003
Staphylococcus aureus - ATCC 6538	Siqura EF4850	ASTM E2149	24h	Interface	M13-163
Staphylococcus aureus subsp. Aureus Rosenbach - ATCC 33591	Siqura EF3851	ASTM E2149	24h	Interface	M12-029A
Staphylococcus aureus - ATCC 6538	Siqura EF3851	AATCC 100	24h	Interface	M14-133
Escherichia Coli - ATCC 25922	Siqura EF3851	AATCC 100	24h	Interface	M14-133
Dermatophagoides Farinae (Dustmite)	Freche EF4850Z	GB/T 24253	18h	SGS	ASH15-018839-10
Escherichia coli - ATCC 8099	Freche EF4850Z	FZ/T 73023	18h	STS	ASH15-018839-04
Staphylococcus aureus - ATCC 6538	Freche EF4850Z	FZ/T 73023	18h	STS	ASH15-018839-04
Candida albicans ATCC-10231	Freche EF4850Z	FZ/T 73023	18h	STS	ASH15-018839-04

REGULATORY APPROVALS

Siqura products hold regulatory approvals for markets that we operate.

Examples of regulatory approvals.

- TGA
- APVMA
- European BPR
- US EPA
- OEKOTEX
- NZFSA

Please contact us for further information of our regulatory approvals.

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