



# Frequently Asked Questions

## Stepan Biocide Products

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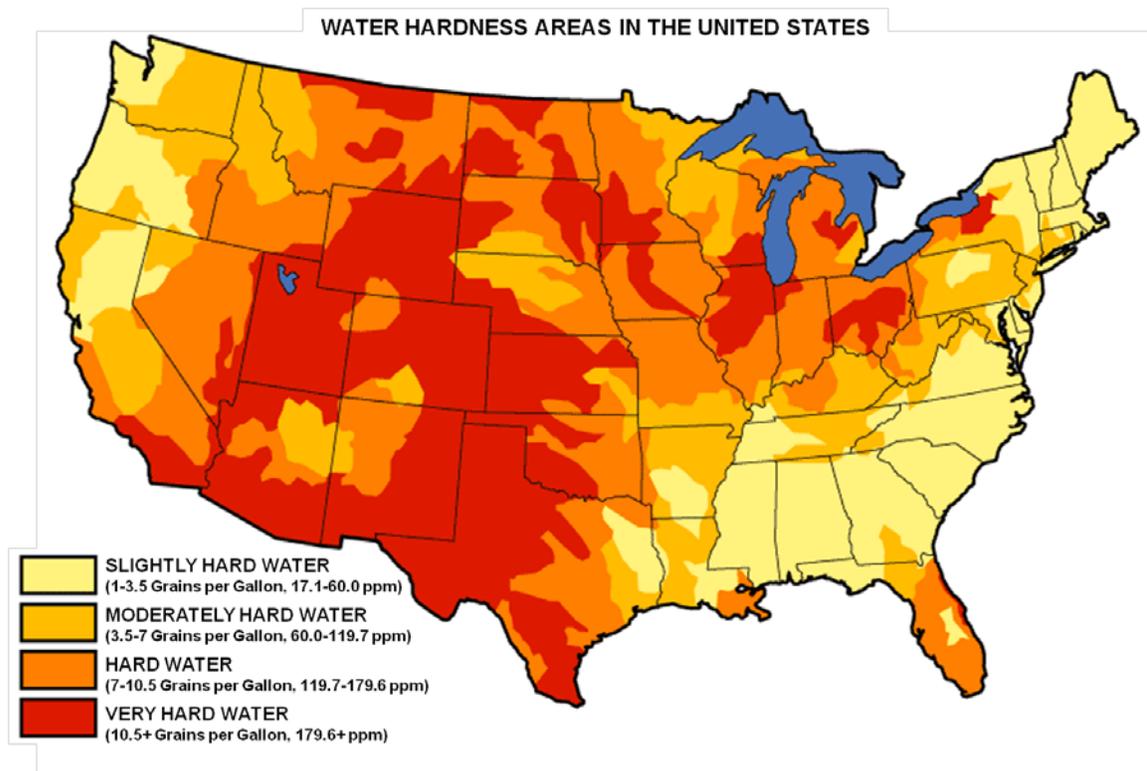
## THE BASICS

### How do germicidal quaternaries kill microorganisms?

Germicidal quaternaries carry a positive charge. Surfaces of microorganisms (algae, bacteria, fungi, and viruses) carry a negative charge. When a germicidal quaternary is applied, the positively-charged quaternary attaches itself to the negative sites on the organism's cell surface. This results in the disruption of the organism's cell surface and eventual death.

### Why should I care about hard water tolerance? Are Stepan end-use disinfectant and sanitizer formulations hard water tolerant?

Hard water ions are Calcium ( $\text{Ca}^{+2}$ ) and Magnesium ( $\text{Mg}^{+2}$ ). These are cations and as such can diminish quaternary efficacy by competing with the positively-charged quaternary for attachment to the negative sites on the microorganism's cell surface. This is commonly referred to as the "competing ion effect".



Typical hard water tolerance claims for hospital disinfectants (dilutable concentrates) can range from 200 ppm to 400 ppm (as  $\text{CaCO}_3$ ). Sanitizer water hardness tolerance can be between 200-1000 ppm. Food contact sanitizers (dilutable concentrates) must list a hard water tolerance limit on their label. The state of Wisconsin requires a minimum of 500 ppm hard water tolerance for food contact surface sanitizers.

### Why should I care about contact time?

The shorter the contact time, the shorter the time needed to disinfect the surface. The maximum allowable contact time for a disinfectant is 10 minutes. The required contact time for food contact surface sanitizers is one minute. For non-food contact sanitizers, the contact time cannot be longer than five minutes.

Stepan offers disinfectants with a shorter contact time.

Short Contact Disinfectant/Cleaner Product Family		
Product Name		Form
<i>5-Minute and Faster Hospital Disinfectant/Cleaner</i>		
Detergent Disinfectant Spray	(1839-83)	Ready-to-Use Spray
Stepan Disinfectant Wipes	(1839-190)	Ready-to-Use Wipe
SC-RTU Disinfectant Cleaner	(1839-220)	Ready-to-Use Spray

### I have heard my customer mention that they want to purchase a certain quat “generation” (e.g. fifth generation quat). What does this mean and what generations of quats are sold by Stepan Company?

Quaternary ammonium compounds and their respective chemistries can be classified by generation. This classification is loosely tied to the order in which they were introduced to the market. Stepan offers an extensive line of first, third, fourth and fifth generation quats. The second generation ADEBAC chemistry has never been commercially sold by itself, thus why it has not been included in the second table.

Acronym	Chemistry
ADBAC	Alkyl dimethyl benzyl ammonium chloride
ADEBAC	Alkyl dimethyl ethylbenzyl ammonium chloride
ADBAC/ADEBAC	Alkyl dimethyl benzyl ammonium chloride/ Alkyl dimethyl ethylbenzyl ammonium chloride
DDAC	Dialkyl dimethyl ammonium chloride
DDAC/ADBAC	Dialkyl dimethyl ammonium chloride/ Alkyl dimethyl benzyl ammonium chloride

Generation	Chemistry	Example of Stepan Active	Cost	Hard Water Tolerance	Fungal Activity
First	ADBAC	BTC® 8358	Lowest	Lowest	Lowest
Third	ADBAC/ADEBAC	BTC® 2125M-80%	Medium	Better	Medium
Fourth	DDAC	BTC® 8188	Highest	Best	Best
Fifth	DDAC/ADBAC	BTC® 1210-80%	High	Better	Better

## GENERAL TERMINOLOGY

### What is “broad spectrum” efficacy?

The EPA’s definition of a “broad spectrum” disinfectant is one that has public health claims for all three of the major classes of organisms:

- Bacteria – effective against gram-negative and gram-positive bacteria
- Fungi – effective against at least one pathogenic fungus (usually *Trichophyton mentagrophytes*)
- Viruses – effective against pathogenic viruses (at least one enveloped virus, such as Influenza A or one non-enveloped virus, such as Adenovirus)

If the above criteria are met, a disinfectant can make an unqualified “kills germs” claim on its label. Sanitizers are not considered broad spectrum by EPA’s definition since they are only meant to reduce bacteria levels.

### When would I use an EPA-registered manufacturing use product (MUP) such as BTC®, SO/SAN® or ONYXIDE® versus a STEPANQUAT® product?

The sole purpose of BTC® products is for use as active ingredients in the formulation of EPA-registered end use products (e.g. as disinfectants, sanitizers, water treatment microbiocides, swimming pool algaecides). STEPANQUAT® products are cationic surfactants that can be used in hard surface cleaners (e.g. as an anti-stat or to assist with degreasing). The products STEPANQUATs are formulated into do not make pesticidal claims and, consequently, are not required to be registered as a pesticide with the U.S. EPA.

## BACTERIA

### What is the difference between “Gram-positive” and “Gram-negative” bacteria? It is a classification of bacteria based on their staining properties.

**Gram-positive** bacteria are those that are stained dark blue or violet by gram staining. Examples would be *Bacillus*, *Listeria*, *Staphylococcus*, *Streptococcus*, *Enterococcus*, and *Clostridium*.

**Gram-negative** bacteria do not stain dark blue or violet by similar staining technique. The proteobacteria are a major group of Gram-negative bacteria and example of these would be *Escherichia coli*, *Salmonella*, and other Enterobacteriaceae, *Pseudomonas*, *Moraxella*, *Helicobacter*, *Stenotrophomonas*, *Bdellovibrio*, acetic acid bacteria and *Legionella*.

## What are antibiotic resistant bacteria? Are Stepan end-use disinfectant formulations effective against antibiotic resistant bacteria?

Antibiotic resistant bacteria are bacteria not inactivated by antibiotics. Stepan has multiple end-use product registrations available for subregistration that are effective against known antibiotic resistant bacteria such as those listed below.

Antibiotic Resistant *Escherichia coli*  
Antibiotic Resistant *Klebsiella pneumoniae*  
Antibiotic Resistant *Staphylococcus epidermidis*  
Extended Spectrum Beta-Lactamase (ESBL) *Escherichia coli*  
Methicillin Resistant *Staphylococcus aureus* (MRSA)  
Multi-Drug Resistant (MDR) *Acinetobacter baumannii*  
Oxacillin Resistant *Streptococcus pneumoniae*  
Vancomycin Intermediate Resistant *Staphylococcus aureus* (VISA)  
Vancomycin Resistant *Enterococcus* (VRE)

## GENERAL DISINFECTION

### What is the difference between “disinfectants” and “sanitizers”? What is a “sterilant”? Does Stepan carry all of these products?

A **sanitizer** reduces bacteria on a hard surface to a level that is considered safe by public health organizations. A food contact surface sanitizer reduces bacterial contamination by 99.999% (log five reduction in one minute). A non-food contact surface sanitizer reduces bacterial contamination by 99.9% (log three reduction in less than or equal to five minutes).

A **disinfectant** kills all bacteria which are claimed on the product label.

A **sterilant** kills all bacteria and spores on environmental surfaces. Quaternaries are not sterilants since they are not effective against spores.

Stepan does not offer any sterilants as part of their antimicrobial line.

### What is the difference between a “limited disinfectant”, “general disinfectant”, and “hospital disinfectant”?

You can determine a “limited”, “general”, or “hospital” disinfectant by the microorganisms listed on the label.

**Limited** must be supported by efficacy testing against either *Salmonella enterica* or *Staphylococcus aureus*

**General** must be supported by efficacy testing against both *Salmonella enterica* and *Staphylococcus aureus*

**Hospital** must be supported by efficacy testing against *Staphylococcus aureus*, *Salmonella enterica* and *Pseudomonas aeruginosa*

### **What are the label language requirements for each class of disinfectant?**

A **limited** disinfectant must have the statement “Limited Disinfectant” displayed on the front panel of the label.

A **general** disinfectant is not required to state “General Disinfectant” on the front panel or anywhere on the label. The use sites and the organism claims define the general disinfectant. A general disinfectant cannot have medical use sites on the label.

A **hospital** disinfectant will list medical use sites on the label. The label will usually state “Hospital Disinfectant” or “Hospital Grade Disinfectant” or “Meets the requirements for a Hospital Disinfectant”. These statements, such as “Hospital Disinfectant,” are not required on a hospital disinfectant label.

A limited disinfectant is the only class of disinfectants that requires a statement on the front panel of the label.

### **What does “one-step disinfectant” mean? Are Stepan end-use disinfectant formulations “one-step”?**

“One-step disinfectant” means to clean and disinfect in one operation.

All of Stepan’s end-use disinfectant registrations are tested in the presence of five percent (5%) organic load and are considered one-step cleaner/disinfectants. Five percent organic load simulates a lightly soiled surface.

NOTE: EPA requires that all disinfectants carry the following label direction: “For heavily soiled areas, a pre-cleaning step is required.”

### **What is a “neutral disinfectant”? Should I be using a “neutral disinfectant”? Are all “neutral disinfectants” the same?**

The term neutral refers to the pH of the disinfectant. The pH is a measure of the acidity or alkalinity of a solution, numerically equal to 7 for neutral solutions, increasing with increasing alkalinity and decreasing with increasing acidity. The common pH scale is from 0 to 14. A neutral disinfectant could have a pH as low as 6 and as high as 8.5.

Whether or not a customer should be using a neutral disinfectant is dependent on their end-use application. Neutral disinfectants are less likely to dull high gloss floor finishes with repeated use. Typically, medical care facilities prefer neutral disinfectant cleaners. Not all neutral disinfectants are the same. The use dilution, active ingredient(s) and/or surfactant (cleaning agents) could be different.

Stepan's neutral pH disinfectant cleaner registrations are:

EPA Reg. No. 1839-	Registration Name
93	Powdered Detergent/Disinfectant (neutral version)
112	PT 4.0 Pine Scent Disinfectant Detergent
166	BTC® 885 Neutral Disinfectant Cleaner-128
167	BTC® 885 Neutral Disinfectant Cleaner-256
168	BTC® 885 Neutral Disinfectant Cleaner-32
169	BTC® 885 Neutral Disinfectant Cleaner-64
214	SC-NDC-256
215	SC-NDC-128
216	SC-NDC-64

**Why would a customer want to use an acidic (low pH) disinfectant/sanitizer?**

In some cases, such as clean-in-place (CIP) dairy cleaners/sanitizers, toilet bowl cleaners, and bathroom tile cleaners, acidic conditions are required to remove mineral deposits (e.g. lime and rust) and stains by making the components more soluble.

Stepan's acid (low pH) disinfectants/sanitizers are:

EPA Reg. No. 1839-	Registration Name
51	Acid CD Dairy & Food Processing Cleaner and Sanitizer
104	Household Light Industrial Type Germicidal Acid Bowl Cleaner
105	Industrial Type Germicidal Acid Bowl Cleaner

**Why would a customer want to use an alkaline (high pH) disinfectant/sanitizer?**

Highly soiled and/or greasy surfaces are more easily cleaned with an alkaline product.

Stepan's alkaline (high pH) disinfectants are:

EPA Reg. No. 1839-	Registration Name
78	NP 3.2 Detergent/Disinfectant
79	NP 4.5 Detergent/Disinfectant
80	NP 12.5 Detergent/Disinfectant
83	Detergent Disinfectant Pump Spray
84	Aerosol Detergent/Disinfectant
94	NP 3.2 (D&F) Detergent/Disinfectant
95	NP 4.5 (D&F) Detergent/Disinfectant
96	NP 9.0 (D&F) Detergent/Disinfectant
97	NP 12.5 (D&F) Detergent/Disinfectant
211	SC-AHD-64
212	SC-AHD-256
213	SC-AHD-128
220	SC-RTU Disinfectant Cleaner

NOTE: For all three responses on disinfectant type (acidic, neutral, and alkaline), the pH noted is at end-use dilution.

## SANITIZATION

### **Are antibacterial hand soaps and hand sanitizers regulated by the US EPA or FDA?**

Antibacterial hand soaps and hand sanitizers are considered drugs and regulated by the US FDA under the 1994 Tentative Final Monograph (TFM). The way the TFM is currently written, the requirements for efficacy are geared toward a patient preoperative skin preparation, surgical hand scrub, health care professional handwash and antiseptic handwash. These categories have very stringent requirements, more than necessary for a consumer hand wash.

Stepan offers an antibacterial hand soap concentrate, **STEPANOL® ABHS-15C**. When formulated at a 3:1 dilution with water, **STEPANOL® ABHS-15C** will produce a clear, very mild and good foaming hand soap.

Stepan offers **STEPANQUAT® 50 NF** and **STEPANQUAT® 65 NF**, both Benzalkonium chloride solutions, for broad spectrum preservation of personal care and pharmaceutical products such as eye contact lens solution and topical antiseptics.

### **Does Stepan have a recommended non-alcohol hand sanitizer formulation?**

Stepan can suggest a starter formulation for a non-alcohol foaming hand sanitizer that is stable up to 40°C. This product would be regulated by U.S. FDA (or similar authorities in the respective countries) and the manufacturer would be responsible for ensuring compliance with all regulatory requirements. For example, in the United States, the manufacture of the finished product is obligated to meet cGMP requirements, obtain a drug manufacturing license and comply with a drug facts label.

## FOOD CONTACT

### **What is the difference between a “food contact surface sanitizer” and a “non-food contact surface sanitizer”?**

A food contact surface sanitizer - At a minimum, reduces the level of *Staphylococcus aureus* and *Escherichia coli* by 99.999% on a food contact surface within one minute. All ingredients must be cleared under 40 CFR 180.940 (*tolerance exemption for actives and inerts for use in antimicrobial formulations [food contact surface sanitizing solutions]*).

### **A potable water rinse is not allowed after sanitization of a food contact surface.**

CAUTION: Indicating on the label a potable water rinse is “not required” is an incorrect interpretation. No rinse is allowed.

A non-food contact surface sanitizer - At a minimum, reduces the level of *Staphylococcus aureus* and *Klebsiella pneumoniae* or *Enterobacter aerogenes* by 99.9% on non-food contact surfaces within five minutes.

### **What does “potable water rinse” mean and are there label instructions for how much water is necessary to effectively rinse the surface?**

In simple terms, potable water means of sufficient quality that can be consumed (drinking water). There is no formal potable wash rinse ratio or guideline. We recommend that the end user rinse as they would any other surface to ensure no residue is left on a food contact surface. For example, rinsing soap off of a dish.

Remember: a potable water rinse is not allowed after sanitization of a food contact surface.

### **What is the maximum allowable active quaternary concentration on a food contact surface without a potable water rinse?**

The maximum allowable active quaternary on a food contact surface without a potable water rinse is 400 ppm (40 CFR 180.940). To clarify, the 400 ppm maximum level is for the end-use level after you have diluted the product.

### **What is a “third sink” sanitizer?**

Sanitization in public eating establishments and small food processing areas requires three steps:

1. a detergent wash,
2. a potable water rinse, and
3. immersion in the sanitizing solution.

This process is usually performed in a three-compartmental sink. In order to sanitize cleaned and rinsed food, contact equipment (e.g. a glass, plate, small grinder, utensils) must remain in the sanitizing solution for one minute and then be allowed to air dry.

## **CLAIMS**

### **What is the difference between a “public health” claim and a “non-public health” claim?**

A public health claim is control of a microorganism which is pathogenic to humans. Control of a human pathogenic organism, such as *Staphylococcus aureus*, constitutes a public health claim.

A non-public health claim is the control of a non-human pathogen. For example, an animal pathogen such as canine parvovirus, an aesthetic claim such as swimming pool algacide, control against bacteria that causes spoilage, deterioration or fouling of materials such as paint or industrial fluids.

### **Can you provide me with an example of some emerging pathogens? Will Stepan continue to update their labels to reflect emerging pathogens?**

As of 2011, the following are example of emerging pathogens:

- Ebolavirus
- Enterovirus D68
- Avian Influenza A (H7N9) Virus
- *Klebsiella pneumoniae* New Delhi Metallo-Beta Lactamase (NDM-1) Carbapenem Resistant
- MDR *Acinetobacter baumannii*
- *Escherichia coli* with extended beta-lactamase resistance (ESBL)
- Enterotoxigenic *Escherichia coli*
- Community & Hospital Associated MRSA
- MDR/XDR *Mycobacterium tuberculosis*
- Still Hot.....Community & Hospital Associated MRSA, Norovirus

Stepan’s Antimicrobial Team continually monitors emerging pathogens based on customer input, World Health Organization (WHO) and Center for Disease Control (CDC) updates and through contract microbiology lab relationships.

You will receive a formal communication when we add new pathogens to any of our existing registrations. Contact your Stepan local sales representative if you have an interest in a subregistered product with a particular claim.

**Do you have any end-use registrations with claims against blood borne pathogens (HIV, HBV and HCV)?**

Yes, Stepan has many end-use registrations for subregistration that have claims against these blood borne pathogens. We have invested and continue to invest in the addition of blood borne pathogen claims on our subregistration labels. Noted are those registrations that contain a claim against one or more blood borne pathogens:

<b>EPA Reg. No. 1839-</b>	<b>Registration Name</b>
78	NP 3.2 Detergent/Disinfectant
79	NP 4.5 Detergent/Disinfectant
80	NP 12.5 Detergent/Disinfectant
81	NP 9.0 Detergent/Disinfectant
83	Detergent/Disinfectant Pump Spray
84	Aerosol Detergent/Disinfectant
86	BTC® 2125M 10% Solution
93	Powder Detergent/Disinfectant
94	NP 3.2 (D&F) Detergent/Disinfectant
95	NP 4.5 (D&F) Detergent/Disinfectant
96	NP 9.0 Detergent/Disinfectant
97	NP 12.5 (D&F) Detergent/Disinfectant
155	BTC® 2125M 20% Solution
166	BTC® 885 Neutral Disinfectant Cleaner-128
167	BTC® 885 Neutral Disinfectant Cleaner-256
168	BTC® 885 Neutral Disinfectant Cleaner-32
169	BTC® 885 Neutral Disinfectant Cleaner-64
174	STEPAN® Towelette
190	STEPAN® Disinfectant Wipe
211	SC-AHD-64
212	SC-AHD-256
213	SC-AHD-128
214	SC-NDC-256
215	SC-NDC-128
216	SC-NDC-64
220	SC-RTU Disinfectant Cleaner

**What if I want to add a blood borne pathogen to my label?**

It is a possibility. However, adding a blood borne pathogen is expensive and will take a minimum of 6-8 months to complete efficacy, data review and adding the claim to the Federal EPA label. If interested in adding to a particular label, please outline your requirement and initiate through your Stepan sales representative. Business management review and approval is required.

**Does Stepan have any end-use registrations that are tuberculocidal?**

Yes, we have two registrations effective against Tuberculosis. They are:

<b>EPA Reg. No.</b>	<b>Registration Name</b>	<b>Contact Time</b>
1839-83	Detergent Disinfectant Pump Spray	5 minutes
1839-174	STEPAN® Towelette	10 minutes

**Does Stepan have any registrations that can claim residual efficacy?**

Stepan does not offer any quaternary disinfectants that claim residual efficacy. We continue to explore the area of residual efficacy and will inform our customers as we proceed.

**REGISTRATION**

**What is a manufacturing-use product (MUP)? What is an end-use product (EUP)?**

A manufacturing-use product is an active ingredient used in an end-use antimicrobial product. Stepan markets and sells MUPs under the BTC®, SO/SAN®, ONYXIDE® tradenames. An end-use product (EUP) is an EPA-registered product that makes antimicrobial claims. Stepan registers end-use products with BTC®, SO/SAN®, and ONYXIDE® as the active ingredients. Stepan does not manufacture end-use products. We allow our customers to subregister our end-use registrations so they can market and sell EPA end-use registered products.

**Are all Stepan antimicrobials (MUP and EUP) registered with the U.S. EPA? What about state registrations?**

Yes. If sold in the United States, all antimicrobial pesticides (Stepan antimicrobials included) are legally required under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to be registered with the U.S. EPA. If one markets a pesticide in a state that requires a pesticide registration, said pesticide (MUP, EUP) must be registered in that state. For MUPs, some states only require U.S. EPA pesticide registration. For EUPs, states require simple paperwork completion and payment of registration fees while others, specifically California, require registration review similar to U.S. EPA plus a registration fee.

**Can I use a registered alternate source of active from another supplier to save money?**

No. Formulators of registered pesticides must use the registered source of active ingredient from the supplier as specified on the EPA-approved confidential statement of formula (CSF).

**May I register my own end-use antimicrobial product?**

A company may choose to register their own end-use antimicrobial product. However, if the company so chooses to register their own end-use antimicrobial product, they are responsible for their own efficacy, chemistry and acute toxicology performed under good laboratory practices (GLP). This process is costly and time-consuming, thus the advantage of subregistering with Stepan Company!

### If I subregister from Stepan, am I obligated to register in all 50 states?

You are required to register in all states where your product is sold. Please note, it is your obligation to obtain and maintain these registrations.

### Does Stepan sell any wipe products?

Stepan Company has available two end-use quaternary wipe formulations for the wipes market.

	<b>Stepan Disinfectant Wipes</b> EPA Reg. No. 1839-190	<b>Stepan Towelette</b> EPA Reg. No. 1839-174
<b>Value Proposition</b>	<b><i>Hospital to Home Fast Kill Disinfectant</i></b>	<b><i>Hospital TB Grade Disinfectant</i></b>
<b>Formulation Feature</b>	Quat-based (Alcohol/Bleach Free)	Quat-based (Alcohol/Bleach Free)
<b>Target Market(s)</b>	Hospital Jan-San Home	Healthcare
<b>Type of Kill</b>	Disinfectant and Sanitizer	Disinfectant
<b>Kill Profile</b>	Bactericidal Virucidal Fungicidal	Bactericidal Virucidal Tuberculocidal
<b>Speed of Kill</b>	5-minute Sanitization Kills 99.9% Bacteria in 15 seconds	10-minute Disinfection

### Do we know of particular types of substrates that cannot be used based on quat uptake?

There is no established “do not use” list. Quat-substrate interaction can vary (depending on the natural fiber content of the substrates) and formulators of Stepan wipes must use one of the approved substrates as listed in the manufacturing procedure.

### Does Stepan offer any aerosol end-use registrations?

Yes, we do. Stepan has EPA Reg. No. 1839-84, Aerosol Detergent Disinfectant available for subregistration.

### Does Stepan have an end-use registration that kills *Clostridium difficile* (C. diff)?

At present, Stepan does not have an end-use registration that is effective against the spore form of C. diff.

## LABELING

### **There is too much label language to fit on my bottle. Can I take off some of this label language?**

Stepan has an EPA-approved master label with a multitude of claims and end-use sites. Not all of which are required to be on your in-commerce label. We recommend you reference the *EPA Label Review Manual* at <http://www.epa.gov/oppfead1/labeling/lrm/> and *Pesticide Labeling FAQs* at <http://www2.epa.gov/pesticide-labels/pesticide-labeling-questions-answers> for label sections that are required. Any changes made to a label need to be approved by Stepan prior to use.

### **Are the first-aid statements required to be on the front panel under the signal word? I cannot fit it on the front of my bottle.**

On all pesticide labels with a DANGER signal word, first-aid statements must be placed immediately under the DANGER on the front panel. This has been a final rule of the US EPA since December 14, 2001.

### **I'd like to change a few words on the label so that the precautions don't sound so severe. Is that okay?**

No. Precautionary statements, signal words, first-aid, and disposal statements must be stated word for word as has been approved on Stepan's EPA-approved master label.

### **Can I use my own tradename on a subregistered product label?**

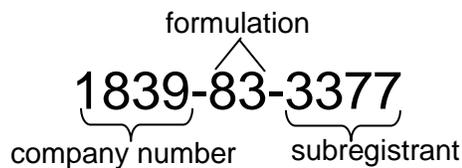
Yes. However, the name must be reviewed and approved by Stepan Company prior to use.

### **If new claims are added to a Stepan label, how will I know? Am I obligated to add these claims? Is the same true for precautionary statements?**

Stepan's Antimicrobial Team will notify all Stepan subregistrants when a label has been revised. In most cases, subregistrants are not obligated to add a microorganism claim. They are obligated to revise precautionary, first-aid, disposal, and changes in signal word to correspond with the updated Stepan master label.

### **What are EPA product numbers? What are EPA establishment numbers?**

An EPA product number provides the following information:



Related to an EPA Establishment Number (e.g. 1658-MO-1), the "1658" is the company number, the MO is the manufacturing site as Missouri and "1" is the assigned pesticide manufacturing/production site.

### **If I subregister with Stepan, will Stepan help me with technical and regulatory questions related to this product?**

Yes, we have an extensive support staff of regulatory, technical and business professionals to assist you with any questions that you may have. We pride ourselves on our market, technical and regulatory knowledge.

### **What is the timing and cost associated with adding a new “bug” to a product label?**

Depending on the organism (bacteria, virus, fungi) and the form of the product (wipes, RTU, dilutable concentrates) the cost of efficacy testing can vary greatly. Efficacy testing can take up to 3 months. Once efficacy is complete, a label amendment must be submitted. Review time is 4 months. The cost associated is the Pesticide Registration Improvement Act fee (PRIA fee).

## **FORMULATION QUESTIONS**

### **Can I add bleach to BTC® 2125M or any registered BTC® product?**

From a regulatory standpoint, remember that BTC® 2125M is a registered manufacturing- use product. It is used as an active ingredient in an end-use product registration. Its sole use is to be formulated into an end-use registration. It is not to be altered prior to formulation.

From a safety standpoint, adding household bleach (5% Sodium hypochlorite) to BTC® 2125M or any concentrated quaternary would result in a hazardous chloramine reaction.

### **Can anyone formulate an EPA regulated end-use registration?**

It is important to note that Stepan requires potential formulators to meet some basic competencies including, but not limited to, verification of the first three lots of manufactured product, on-site analytical testing and detailed record keeping.

### **Does Stepan sell any biocidal actives other than quaternary ammonium compounds for disinfection/sanitization (i.e. thyme oil)?**

Not at this time.

### **Does Stepan sell any preservatives?**

Stepan does offer **ONYXIDE® 200 PRESERVATIVE**, a triazine compound, as a metalworking fluid preservative, oil field applications preservative and as a preservative for emulsions, adhesives and inks (non-food use).

### **Why do I see products labeled as “mold stain or mildew stain removers” on the market without a U.S. EPA registration?**

Cleaning or removing a stain from algae, mold, mildew or other organisms is not pesticidal. Stain is a color, not an organism. A color arises from conjugated double bonds within organic compounds. Typically, acids are used to break the bonds in colors (ACC & CSPA’s Response to Cleaning Claims Fact Sheet 1-10-11). Therefore, why Stepan Mold Stain and Mildew Stain Remover (Formulation# 1116) on Stepan website does not require an EPA registration.

### **How do I know that Stepan end-use registrations really work?**

In order to register an antimicrobial product, efficacy data to support the claims made on the label must be provided and reviewed by the U.S. EPA. Efficacy data is available upon request.

### **Can I substitute an alternative supply of ingredient than that listed on the Stepan Manufacturing-Use Procedure?**

No. The formulator is legally required to use only those ingredients/suppliers identified on the EPA-approved Confidential Statement of Formula (CSF) and the corresponding Stepan Manufacturing-Use Procedure.

Any substitution can subject a formulator to an EPA fine and Stop Sale and Recall Order (SSURO).

## SAFETY

### **Why are some Stepan antimicrobials marked “Caution” while others are marked “Warning” or “Danger”?**

Each label will display a prominent signal word that indicates the relative toxicity of the end-use product. The three signal words, in order of increasing toxicity, are **Caution**, **Warning** and **Danger**. A signal word must appear on the front panel of the label. Products with a **Caution** signal word are slightly toxic. Products with a **Warning** signal word are moderately toxic. Products with a **Danger** signal word are highly toxic/corrosive. The signal word is based on a toxicity profile as determined by the required acute toxicity tests: acute oral, acute dermal, acute inhalation, eye irritation, skin irritation and dermal sensitization (commonly referred to as the “acute six pack”).

### **What is “personal protective equipment” (PPE) and why do I need it when using a antimicrobial end-use product?**

PPE includes all clothing and other work accessories designed to protect an individual against workplace hazards. Examples of PPE would include safety goggles, gloves, respirators, aprons, and work boots. When using an antimicrobial, consult your FIFRA label for proper PPE.

## BUSINESS SUPPORT/DECISIONS

### **Will Stepan support the U.S. EPA Reregistration Eligibility Decision (RED) for ADBACs and DDACs?**

Yes. Stepan is fully committed to supporting the registration of ADBAC and DDAC quaternaries. We are a member of the ADBAC/DDAC consortium. This consortium was formed to generate all of the toxicological and environmental fate data to support the quaternary reregistration. We are also members of two exposure task forces: Antimicrobial Exposure Assessment Taskforce (AEATF II) and Antimicrobial Exposure Joint Venture (AEJV). These taskforces were formed to generate both occupational and residential exposure data to antimicrobial pesticides in order to aid U.S. EPA in developing risk assessments as part of the RED.

### **Is Stepan supporting biocides in Europe under the Biocidal Products Regulation (BPR)?**

Stepan has notified seven actives substances under separate CAS numbers for the Biocidal Products Directive/Regulation, and has every intention of supporting these actives until their approval under numerous biocidal Products Types (PTs) as the Directive/Regulation progresses. Any questions concerning biocidal legislation within Europe should be directed to Nicolas Plantade of our Stepan Europe Regulatory Affairs Department ([nicolas.plantade@stepaneurope.com](mailto:nicolas.plantade@stepaneurope.com)).

## DYE AND FRAGRANCE QUESTIONS

### **What dyes and fragrances can be used in food contact surface sanitizers?**

You cannot use a fragrance in a food contact surface sanitizer. You can only use food, drug and cosmetic grade (FD&C) dye in food contact surface sanitizers. The U.S. EPA does not allow non-FD&C dyes or fragrances that may adulterate the food products that come in contact with the surface.

All approved dyes will be listed on the confidential statement of formula or manufacturing procedure for each specific food contact surface sanitizer.

### **I've got a terrific in-house fragrance which differentiates my product from the competition. I want to substitute my fragrance for your fragrance. What do I need to do?**

Not all fragrances are the same. Some may affect the quat efficacy. For each fragrance and dye, you need to do a 30-day storage stability, confirmatory efficacy and if going to be added to the Confidential Statement of Formula, components need to be approved on the EPA inerts list.

### **Can I get a new fragrance or dye listed on a Stepan registration so I'll have a unique product for my end-use customers?**

Stepan business management is required to review and approve. In order to add a fragrance and/or dye to a non-aerosol registered end-use product, Stepan must submit an amendment to the U.S. EPA. EPA timing for such an amendment is 90 days without a PRIA review fee. Prior to submitting said amendment, Stepan completes a 30-day storage stability and confirmatory efficacy tests. Due to the costs (lab time and possible outside testing fees) to support an addition of a new dye or fragrance, Stepan may look to the requestor to support the financial expenses to add the dye or fragrance.

For an aerosol end-use product, EPA requires the review of confirmatory efficacy data. These data must be generated under good laboratory practices (GLP). The EPA review period for these data is 120 days with an associated current PRIA review fee. Due to the costs (lab time and possible outside testing fees) to support an addition of a new dye or fragrance, Stepan may look to the requestor to support the financial expenses to add the dye or fragrance.

## U.S. EPA

### **Why does the EPA's Office of Pesticide Programs (OPP) regulate pesticides?**

The EPA safeguards the general public as congressionally mandated by the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). EPA is responsible for insuring that pesticides are safe and effective when used as directed. Agricultural pesticides, insecticides, fungicides, rodenticides, antimicrobials and biopesticides are the main classes of pesticides regulated by EPA.

### **How does the EPA regulate antimicrobials?**

The EPA reviews all data submissions related to pesticides registrations.

To register an antimicrobial end-use product with the EPA, three types of data are required: efficacy, toxicology, and product chemistry. Efficacy and toxicology data address effectiveness and safety of the end-use product. Product chemistry addresses

the formula composition, manufacturing process, and analytical methods. All data requirements are defined in the Code of Federal Regulations (40 CFR 158).

Satisfying EPA data requirements is the only way to get your end-use antimicrobial product registered.

The EPA regulates quaternary actives (BTC®, SO/SAN® and ONYXIDE® products) by requiring extensive chemistry, ecological toxicity, and mammalian reproductive toxicity data. Satisfying EPA data requirements (specified in 40 CFR 158) is the only way to obtain a registration for a pesticide active.

The EPA periodically requires upgrading of registration data through the reregistration process (RED) to reflect any changes in federal law and improved evaluation techniques. Failing to comply will lead to suspension or revocation of pesticide registrations.

EPA's Office of Enforcement and Compliance Assurance (OECA) deals with serious violations. OECA can levy fines, suspend registrations, revoke registrations, seize property, and arrest offenders anywhere in the US.

**Since EPA registered my end-use product, can I state that the EPA endorses my product?**

No. An EPA registration is a legal requirement under FIFRA. It is not an endorsement of a pesticide product.

## **DEFINITIONS**

If available, definitions are per those set forth by OPPTS 810.2000.

### **Algaecide**

Any substance or mixture of substances intended to kill the number of algae in water.

### **Algistat**

Any substance or mixture of substances intended to inhibit the increase of algal populations.

### **Antibacterial**

Any substance or mixture of substances intended to destroy, eliminate, reduce, mitigate or control the growth or development of bacteria in the inanimate environment.

### **Antibiotic**

A substance derived from mold or bacteria inhibiting the growth of other microorganisms (such as bacteria or fungi). Antibiotics are used to treat infectious diseases.

### **Antifoulant**

Any substance or mixture of substances intended to prevent the biological fouling of underwater structures.

### **Antimicrobial**

An agent that destroys or inhibits the growth or reproduction of bacteria, fungi, protozo, or pathogenic viruses.

**Antimicrobial pesticide**

A pesticide [substance or mixture of substances] that is intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime (FIFRA § 2 (mm)).

**Antiseptic**

A drug product applied topically to the skin to help prevent infection or to help prevent cross contamination (FDA Tentative Final Monograph for Healthcare Drug Products, 1994). Antiseptic products are applied on or in the living body of man or other animals. Antiseptic products are not identified as pesticides and are regulated by the Food and Drug Administration.

**Aseptic**

Free of microbial contamination consistent with FDA 21 CFR 178 for commercial sterilants for aseptic food packaging.

**Bacteria**

One of several different types of microorganisms or germs that multiply by division of a single cell into two bacterial cells.

**Bacteriostat**

A substance or mixture of substances intended to inhibit the growth of bacteria in the presence of moisture. (FIFRA § 4(i)(4)(C)(ii))

**Biocide (also germicide)**

A substance that has the ability to kill microorganisms. When a killing action is implied, the suffix *-cide* (e.g. biocide, bactericide, virucide, etc.) is used, while *-static* (e.g. bacteriostatic, virostatic, etc.) is added when an organism's growth is merely inhibited or it is prevented from multiplying.

**Biofilm**

A dynamic, self-organized accumulation of microorganisms and environmental by-products immobilized on a substrate and embedded in an organic polymer mix. This organic polymer mix is also known by the term "glycocalyx".

**Confirmatory data**

A reduced set of data which may be used to support an application or amendment for registration of a product, or a minor formulation change of a registered product.

**Deodorizer**

A substance or mixture of substances, that are of two basic types:

1. those that intended to prevent, reduce, or delay the formation of odors by acting upon microorganisms which produce them, and
2. those that intended to mask, chemically destroy, or neutralize odors.

Products that claim deodorization by antimicrobial means are subject to registration as pesticides.

**Detergent**

A substance that serves to disperse and remove soil and organic material from surfaces allowing a disinfectant to reach and destroy microbes within and beneath dirt. These products also reduce surface tension and increase the penetrability of water, thereby allowing more organic matter to be removed from surfaces. Quaternary ammonium compound disinfectants have detergent properties.

**Disinfectant**

A substance or mixture of substances intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces or inanimate objects. (FIFRA § 4(i)(4)(C)(iii))

**Fungicide**

A substance or mixture of substances intended to destroy fungi (including yeasts) and/or fungal spores.

**Fungistat**

A substance or mixture of substances intended to inhibit the growth of fungi in the inanimate environment.

**Inert ingredients**

Inactive ingredients that are combined into one statement and include items such as surfactant, dyes or coloring agents, perfumes, and water.

**Master label (also end-use product)**

The end-use product label as registered by Stepan Company. This label is provided to subregistrants as a template for their subregistered end-use product. The master label contains all approved use sites, environmental surfaces, antimicrobial pesticide claims, precautionary statements, first-aid statements and signal words.

**Microbiocide**

Any substance, or mixture of substances, intended to reduce the number of living microorganisms (e.g., virucide-virus, mycobactericide-mycobacteria, algacide-algae; bactericide-bacteria; fungicide-fungi; slimicide-slime-forming microorganisms).  
(See *biocide*)

**Microbiostat**

A substance or mixture of substances intended to control or temporarily prevent the growth of microorganisms (e.g., bacteriostat, fungistat, algistat).

**One-Step Sanitizer/Disinfectant**

A substance or mixture of substances intended to be effective in the presence of light to moderate soil without a pre-clean step in the use directions.

**Preservative**

A substance or mixture of substances intended to inhibit the growth of microorganisms capable of causing biological deterioration of a substance(s)/material(s).

**Quaternary Ammonium Compounds**

Substances derived from the ammonium cation,  $\text{NH}_4^+$ , with one or more hydrogen atoms being replaced by organic groups, and for most purposes prepared as a salt.

**Sanitizer**

A substance or mixture of substances intended to reduce the number of microorganisms on inanimate surfaces, in water or air. (FIFRA § 4(i)(4)(C)(i))

**Slime**

A dynamic, self-organized accumulation of microorganisms and environmental by-products immobilized on a substrate and embedded in an organic polymer mix. This organic polymer mix is also known by the term “glycocalyx”.

**Slimicide**

A substance or mixture of substances intended to reduce the number of slime-forming microorganisms.

**Sporicide**

A substance or mixture of substances intended to irreversibly inactivate bacterial spores in the inanimate environment.

**Sterilant**

A substance or mixture of substances intended to destroy or eliminate all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses.

**Sterilization**

The process, either physical (i.e. extreme heat) or chemical (i.e. ethylene oxide), that destroys all microorganisms including spores.

**Tuberculocide**

A substance or mixture of substances that destroys or irreversibly inactivates tubercle bacilli (e.g. *Mycobacterium*) in the inanimate environment.

**Two-Step Sanitizer/Disinfectant**

A substance or mixture of substances that has not been tested in the presence of soil. The sanitizer/disinfectant use directions must state the need to preclean surfaces prior to sanitizing/disinfecting.

**Virucide**

A substance or mixture of substances that destroys or irreversibly inactivates viruses in the inanimate environment.