

Frequently Asked Questions

BTC®/STEPANQUAT® Quaternaries

Canadian Edition

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?

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

The current maximum hard water tolerance claim for hospital disinfectants is 400 ppm (as CaCO_3). Food contact sanitizers must list a hard water tolerance limit on their label.

Why should I care about contact time?

The shorter the contact time, the shorter the time needed to perform the disinfectant process. The maximum contact time for Stepan's registered disinfectant is 10 minutes and we offer disinfectants with a shorter contact time which allows for labour savings. Sanitizer contact time is less than or equal to 5 minutes.

What is a 'fifth generation quat'? What generation of quats does Stepan market?

First Generation: alkyl dimethyl benzyl ammonium chloride (ADBAC)

Second Generation: alkyl dimethyl ethylbenzyl ammonium chloride (ADEBAC) – never commercially sold alone

Third generation: alkyl dimethyl benzyl ammonium chloride/alkyl dimethyl ethylbenzyl ammonium chloride (ADBAC/ADEBAC)

Fourth Generation: Dialkyl dimethyl ammonium chloride (DDAC)

Fifth Generation: Dialkyl dimethyl/alkyl dimethyl benzyl ammonium chloride (Dialkyl/ ADBAC)

What is important to explain to your customer is that later generations do not necessarily mean improved disinfection efficacy. Stepan markets 1st, 3rd, 4th & 5th generation quats. May 2003 Quat of the Month discusses in more detail. If you would like a copy, please contact Jane Williams, jwilliams@stepan.com.

GENERAL TERMINOLOGY

What is ‘broad spectrum “efficacy”’?

A substance, or mixture of substances, capable of destroying or irreversibly inactivating at a minimum one representative hard to kill non-enveloped virus, and which is expected to inactivate other enveloped and non-enveloped viruses present on environmental surfaces and inanimate objects.

BACTERIA

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

Bacteria which are no longer inactivated by antibiotic levels currently considered to be clinically effective. Bacteria strains that are resistant to antibiotics (Methicillin, Vancomycin and Multi-Drug) include: Methicillin Resistant *Staphylococcus aureus* (MRSA), Community Associated Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin Intermediate Resistant *Staphylococcus aureus* (VISA), Vancomycin Resistant *Enterococcus faecalis* (VRE), Vancomycin Resistant *Staphylococcus aureus* (VRSA), Multi-Drug Resistant (MDR) *Acinetobacter baumannii*.

Stepan Canada registrations with antibiotic resistant organism claims:

BTC® 885 Neutral Disinfectant Cleaner-128	MRSA, VISA, VRE, CA-MRSA, MDR
BTC® 885 Neutral Disinfectant Cleaner-256	MRSA, VISA, VRE, CA-MRSA, MDR
BTC® 885 Neutral Disinfectant Cleaner-32	MRSA, VISA, VRE, CA-MRSA, MDR
BTC® 885 Neutral Disinfectant Cleaner-64	MRSA, VISA, VRE, CA-MRSA, MDR
BTC® 2125M 10% Solution	VISA
Detergent Disinfectant Pump Spray	MRSA, VRSA, VISA, VRE, CA-MRSA
NP 3.2 D&F Detergent Disinfectant	MRSA, VRSA
NP 3.2 D&F Detergent Disinfectant	MRSA, VRSA
NP 9.0 D&F Detergent Disinfectant	MRSA, VRSA
SC QP-64	MRSA, CA-MRSA
SC-RTU	MDR, MRSA, VRE
Stepan® Disinfectant Wipe	MRSA, VRE, VISA, CA-MRSA
Stepan® Towelette	MRSA, VISA, VRE
SC-AHD-64 ^{II} ; SC-AHD-128 ^{II} ; SC-AHD-256 ^{II}	MRSA, VRE, VISA, CA-MRSA, MDR
SC-NDC-64 ^{II} ; SC-NDC-128 ^{II} ; SC-NDC-256 ^{II}	MRSA, VRE, VISA, CA-MRSA, MDR

GENERAL DISINFECTION

What is the difference between ‘disinfectants’ and ‘sanitizers’? What is a ‘sterilant’? Does Stepan carry all of these products?

A sanitizer reduces the level of microorganisms present by significant numbers or to acceptable levels established by federal or provincial health authorities. A food contact surface sanitizer reduces bacterial contamination by 99.999%. A non-food contact surface sanitizer reduces bacterial contamination by 99.9%.

A hard surface disinfectant kills pathogenic and potentially pathogenic microorganisms on hard non-porous inanimate surfaces or inanimate objects.

A sterilant kills all microorganisms 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 does ‘one step disinfectant’ mean? Are Stepan end-use disinfectant formulations ‘one step’?

To clean and disinfectant in one operation.

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

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. A neutral disinfectant could have a pH as low as a 6 and as high as 8.5. Whether or not a customer should be using a neutral disinfectant is dependent on 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.

SANITIZATION

What is a ‘third sink’ sanitizer?

Sanitization processes in public eating establishments and small food processing areas require three steps. The first step is the detergent wash, the second step is a potable water rinse and the third step is 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 (i.e. a glass, plate, small grinder, utensils), it must remain in the sanitizing solution for 1 minute and allowed to air dry.

FOOD CONTACT

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

- a) For public eating establishments, 200 ppm
- b) For food processing establishments, 400 ppm

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 (e.g. *S. typhi*). Identifying a human pathogenic organism constitutes a public health claim. *Staphylococcus aureus* is an example of a pathogenic organism.

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 algaecide, control against bacteria that causes spoilage, deterioration or fouling of materials such as paint or industrial fluids.

Do you have products with claims against blood borne pathogens (HIV, HBV, HCV)?

In Canada an HBV claim requires six lot confirmatory data run by two independent accredited laboratories. As a result, Stepan has no end use registrations in Canada that have an HBV claim. There are many registrations with HIV and HCV claims.

Does Stepan have any registered formulas that are tuberculocidal?

Our patented Detergent Disinfectant Pump Spray is tuberculocidal against *Mycobacterium terrae*. Our Stepan® Towelette has an Intermediate claim against *Mycobacterium bovis*.

Does Stepan have any end use registrations with a claim against Avian Influenza (Bird Flu)?

Currently, the CDC has not released the H5N1 for testing. In order for CDC to release this organism, it must obtain clearance from the FDA. We have many registrations with approved Avian Influenza claims using different organisms.

REGISTRATION

What is a technical active (MUP)? What is a registered formula?

An active ingredient (MUP) is what is used in an end-use (EUP) antimicrobial product. Stepan markets and sells these under the BTC®, SO/SAN®, ONYXIDE® trade names. A registered product is a product registered with Health Canada that makes antimicrobial claims. Stepan does not manufacture EUPs. We allow our customers to reference our registrations so they can market and sell with appropriate regulatory approval.

Who regulates pesticides in Canada?

Canada has two regulatory agencies. The Pest Management Regulatory Agency (PMRA) and the Natural and Non-Prescription Health Products Directorate (NNHPD). PMRA regulates all pesticide products that fall under the Pest Control Products Act. These types of products (cooling tower microbiocides, swimming pool algaecides, insecticides) are issued PCP registration numbers. NNHPD regulates disinfectants under the Food and Drugs Act and issues Drug Identification Numbers (DIN) for disinfectant products. Disinfectants are considered to be drugs in Canada, but are exempt from current good manufacturing procedures (cGMP), subject instead to the *“Standard for the Fabrication, Control and Distribution of Antimicrobial Agents for Use on Environmental Surfaces and Certain Medical Devices”*.

On March 10, 2014 Health Canada published the new Disinfectant Drug Guidelines, broken out into various documents. Refer to <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/index-eng.php>

What does it cost to register a disinfectant in Canada?

A disinfectant can be registered in two ways; as an Administrative DIN (\$310 submission fee) or a Full DIN (\$4137 submission fee). These fees are increased by Health Canada approximately 2% every April 1st.

How do I reference a Stepan registration in Canada?

This is done through the ADMIN DIN process. Contact Jane Williams at 289-337-1651 or jwilliams@stepan.com. She will provide an instruction document, a quick reference list of registered formulas and products bulletins showing the actual formula.

Can I buy an MUP even if it isn't used in a Stepan EUP?

Yes, but the MUP must be used in an EUP of some kind.

FORMULATION QUESTIONS

How do I know that Stepan registered formulas really work?

In order to register an antimicrobial product, efficacy data to support the claims made on the label must be provided to Health Canada for their review and approval.

SAFETY

Why are some Stepan antimicrobials marked 'caution' while others are marked 'warning' or 'danger'?

Signal words and symbol: Each label will display a prominent signal word that indicates the relative toxicity of the registered formula to humans. The three signal words, in order of increasing toxicity, are **caution**, **warning** and **danger**. An applicable signal word must appear on the front panel of the label. Products with a **caution** signal word are slightly toxic orally, dermally or through inhalation. They may cause slight eye and skin irritation. Products with a **warning** signal word are moderately toxic orally, dermally or through inhalation. They cause moderate eye and skin irritation. Products with a **danger** signal word are corrosive to eyes and skin and may be toxic orally, dermally or through inhalation.

LABELLING

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

For an ADMIN DIN submission small changes, such as the removal of statements, claims or verbiage found on the reference label, that are not of interest to the registrant may be made at time of submission. These changes are subject to approval by Health Canada. Significant changes will disqualify the applicant from meeting the requirements of an ADMIN DIN and will necessitate a full DIN submission.

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.

If I reference a Stepan registration to get an ADMIN DIN, 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 to assist you with any questions that you may have. We pride ourselves on our market, technical and regulatory knowledge.

Is Stepan supporting pesticides in Europe under the Biocide Products Directorate (BPD)?

Stepan has notified seven actives under separate CAS numbers for the Biocidal Products Directive, and has every intention of supporting these actives under numerous Category Types as the Directive progresses. Any questions concerning pesticide registration outside of the U.S. and Canada should be directed to North America Technical Service techserv@stepan.com.

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