

Frequently Asked Questions Disinfectants

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 BETCO 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 (dilutable concentrates) is 400 ppm (as CaCO_3). Food contact sanitizers (dilutable concentrates) must list a hard water tolerance limit on their label. Typical sanitizer water hardness tolerance can be between 500-1000 ppm. The state of Wisconsin requires a minimum of 500 ppm hard water tolerance for food contact surface sanitizers.

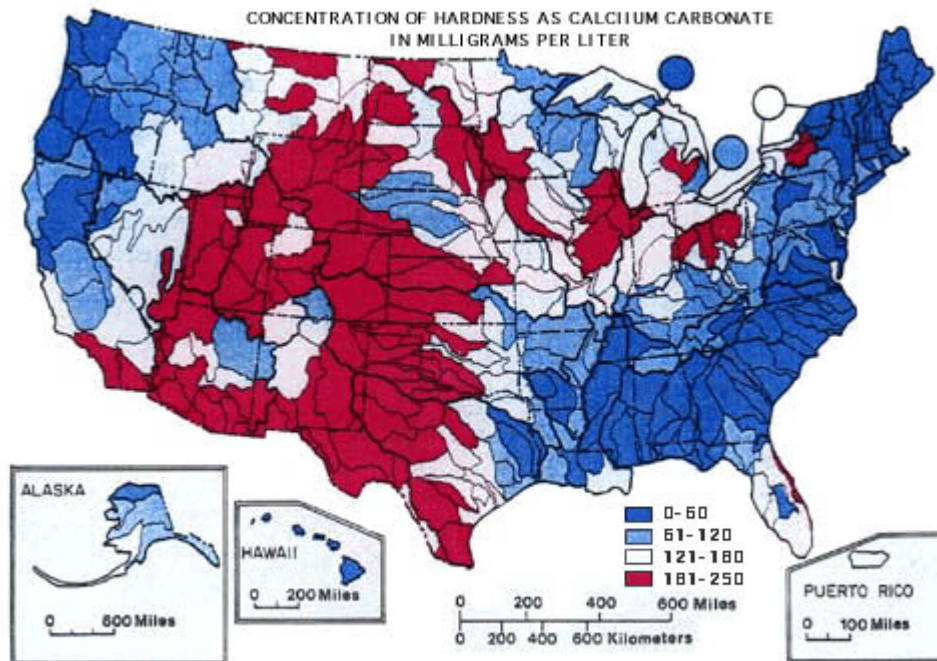


Figure 5.—Mean hardness as calcium carbonate at NASQAN stations during 1975 water year. Map at bottom is colored to show station data representing flow from the accounting unit.



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 a disinfectant is 10 minutes. BETCO offers disinfectants with a shorter contact time. This allows for labor savings. The required contact time for food-contact surface sanitizers is 1 minute. For non-food contact sanitizers, contact time is less than or equal to 5 minutes.

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 fungi (usually Trichophyton mentagrophytes)
- Viruses – effective against pathogenic viruses (at least one enveloped virus such as Influenza A and one non-enveloped virus such as Adenovirus).

Sanitizers are not considered broad spectrum by EPA's definition since they are only meant to reduce bacteria levels.

BACTERIA

What is the difference between 'gram positive' and 'gram negative' bacteria?

Gram-positive bacteria are those that are stained dark blue or violet by gram staining. It includes many well-known genera such as *Bacillus*, *Listeria*, *Staphylococcus*, *Streptococcus*, *Enterococcus*, and *Clostridium*. In contrast to Gram-negative bacteria, which are not affected by the stain. The proteobacteria are a major group of Gram-negative bacteria, including for instance *Escherichia coli*, *Salmonella*, and other Enterobacteriaceae, *Pseudomonas*, *Moraxella*, *Helicobacter*, *Stenotrophomonas*, *Bdellovibrio*, acetic acid bacteria and *Legionella*.

What are antibiotic resistant bacteria? Are BETCO 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 and Vancomycin) include: Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin Intermediate Resistant *Staphylococcus aureus* (VISA) and Vancomycin Resistant *Enterococcus faecalis* (VRE). BETCO has many formulations with claims against antibiotic resistant bacteria. See efficacy chart for more details.



GENERAL DISINFECTION

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

A sanitizer reduces bacteria on environmental surfaces to a level that is considered safe by public health organizations. A food contact surface sanitizer reduces bacterial contamination by 99.999%. A non-food contact surface sanitizer reduces bacterial contamination by 99.9%.

A disinfectant kills all bacteria on environmental surfaces.

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

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

What is the difference between ‘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 cholerasuis* or *Staphylococcus aureus*

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

Hospital – must be supported by AOAC Use Dilution or AOAC Germicidal Spray efficacy testing against *Staphylococcus aureus*, *Salmonella cholerasuis* and *Pseudomonas aeruginosa*

- A “Limited” disinfectant **must have** the statement “Limited Disinfectant” displayed on the front panel of the label.
- A “Hospital” disinfectant will **usually** state that the product is a “Hospital Disinfectant” or “Meets the requirements for a Hospital Disinfectant.” These statements are **not required** for a hospital disinfectant.



What does 'one step disinfectant' mean? Are BETCO end-use disinfectant formulations 'one step'?

To clean and disinfectant in one operation.

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. 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 difference between a 'food contact sanitizer' and a 'non-food contact sanitizer'?

A food contact 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.**

A non-food contact 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 5 minutes.

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

- a) For public eating establishments and dairy processing, 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 algacide, control against bacteria that causes spoilage, deterioration or fouling of materials such as paint or industrial fluids.

Does BETCO have products with claims against blood borne pathogens (HIV, HAV, HBV, HCV)?

Yes, BETCO has many end use registrations that have claims against these blood borne pathogens. See Product efficacy chart for details.

Does BETCO have any end use registrations that are tuberculocidal?

Yes, Fight Bac RTU, TB Plus and TB Plus Spray are all tuberculocidal.

FORMULATION QUESTIONS

How do I know that BETCO end-use registrations really work?

In order to register an antimicrobial product with public health claims, efficacy data to support the claims made on the label must be provided and reviewed by the US EPA.

SAFETY

What is 'personal protective equipment' (PPE) and why do I need it when using a biocide product?

Personal Protective Equipment (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 disinfectant label and MSDS for proper PPE.

LABELING

There is too much label language to fit on my bottle? Can I just take off some of this label language? Yes. However, you may not remove information that relates to the safe use of the material such as the ingredient panel, signal word, precautionary, first aid and disposal statements. You are allowed to remove claims, use sites and environmental surfaces.



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 by the US EPA.

Can I just add symbols to my label such as 'green seal' approval? No. EPA does not allow any logo or seal to an end use product label. Even a separate label is considered "peripheral labeling" and still governed under FIFRA. Even advertisement on the Internet is considered "peripheral labeling." You may add a foreign translation without submitting to EPA for approval.

DYE & FRAGRANCE QUESTIONS

What dye 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 FD&C (food, drug and cosmetic grade) dye in food contact surface sanitizers. The US EPA does not allow non-FD&C colorants 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.

US EPA

Why does the EPA's Office of Pesticide Programs regulate pesticides?

The EPA safeguards the general public as congressionally mandated by FIFRA (Federal Insecticide Fungicide and Rodenticide Act). 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?

Reviews all data submissions related to pesticides registrations. To register an antimicrobial end-use product with 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 (CFR). Satisfying EPA data requirements is the only way to get your end-use antimicrobial product registered.

Regulates quaternary actives by requiring EXTENSIVE chemistry, eco tox, and mammalian reproductive tox data. Satisfying EPA data requirements (specified in the CFR) is the only way to obtain a registration for a pesticide active.



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 a pesticide registrations.

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

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

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

GLOSSARY

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

Algaecide means any substance, or mixture of substances, intended to kill the number of algae in water.

Algistat means any substance, or mixture of substances, intended to inhibit the increase of algal populations. (ASTM E35.15 Draft)

Antibacterial means 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 is a substance derived from mold or bacteria that inhibits the growth of other microorganisms (such as bacteria or fungi). Antibiotics are used to treat infectious diseases.

Antifoulant means 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, protozoa or viruses that are pathogenic.

Antimicrobial Pesticide means 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 means 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 means 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 means 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 or 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 means a dynamic, self-organized accumulation of microorganisms and environmental by-products immobilized on a substrate and embedded in an organic polymer mix (ASTM E35.15 Draft). This organic polymer mix is also known by the term "glycocalyx".

Deodorizer means 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 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 means 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 means a substance, or mixture of substances, intended to destroy fungi (including yeasts) and/or fungal spores.

Fungistat means a substance, or mixture of substances, intended to inhibit the growth of fungi in the inanimate environment.

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



Microbiocide means any substance, or mixture of substances, intended to reduce the number of living microorganisms (e.g., virucide-virus, mycobactericide-mycobacteria, algaecide-algae; bactericide-bacteria; fungicide-fungi; slimicide-slime-forming microorganisms). (See also “biocide.”)

Microbiostat means 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 means 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 means 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, NH_4^+ , with one or more hydrogen atoms being replaced by organic groups, and for most purposes prepared as a salt.

Sanitizer means 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)).

Sporicide means a substance, or mixture of substances, intended to irreversibly inactivate bacterial spores in the inanimate environment.

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

Two-Step Sanitizer/Disinfectant means 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 means a substance, or mixture of substances that destroys or irreversibly inactivates viruses in the inanimate environment.

