

1677-43

1/17/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ron Derbyshire
Senior Manager
Ecolab
370 Wabasha Street North
EUC 9
St. Paul, MN 55102-1390

JAN 17 2014

SUBJECT: Ster-Bac
EPA Registration Number: 1677-43
Application Dated: October 16, 2013
Receipt Date: October 24, 2013

Dear Mr. Derbyshire:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

- Increase Use Rate to 400 ppm for Food Contact Sanitizing per 40 CFR 180.940

Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data. A stamped copy of your labeling is enclosed for your records.

This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulation at 40 CFR 152.3.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415 or Velma Noble at (703) 308-6233.

Sincerely,

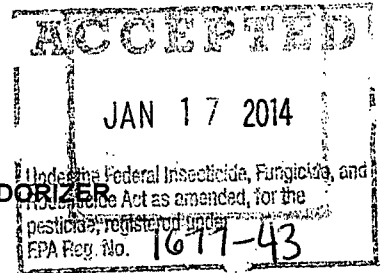
for

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL	SURNAME	DATE						

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STER-BAC

QUATERNARY AMMONIUM SANITIZER - DISINFECTANT - DEODORIZER

ACTIVE QUATERNARY

**INSTITUTIONS - SCHOOLS - RESTAURANTS - FOOD SERVICES -
DAIRIES - BEVERAGE AND FOOD PROCESSING PLANTS**

SMALL FLY OVICIDAL TREATMENT

ALGAE AND SLIME CONTROL IN COOLING AND PROCESS WATERS

ACTIVE INGREDIENT:

n-Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride..... 10.0%

OTHER INGREDIENTS:..... 90.0%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE: Causes irreversible eye damage and skin burns. Harmful if absorbed through the skin and/or swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, protective clothing, and rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS (5 gallon or greater): This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DO NOT MIX WITH ANYTHING BUT WATER

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DEODORIZING

To deodorize waste containers and nonfood areas of food processing plants mix 1 oz **Ster-Bac** per 1 gal. of water. Apply solution with mop, sponge, cloth, or mechanical sprayer to hard surfaces. Allow surfaces to air dry.

GENERAL DISINFECTION

Disinfect previously cleaned hard non-porous surfaces such as walls, floors, sinks, finished woodwork, bathroom fixtures with 1 oz. **Ster-Bac** to 2 gal. of water. Thoroughly wet surfaces with mop, sponge, cloth, or coarse spray. Allow surfaces to remain wet for 10 minutes. Allow to air dry.

GENERAL DISINFECTION OF MEAT, POULTRY, AND OTHER FOOD PROCESSING FACILITIES

Prior to disinfection, food products and packaging materials must be removed from the room or carefully protected. For disinfecting previously cleaned non-porous surfaces such as walls, floors, and sinks, apply use solution of 1 oz. per 1 gallon of water (800 ppm) with cloth, mop, sponge, or sprayer. Treated surfaces must remain wet for 10 minutes. Food contact surfaces that have been disinfected must be rinsed thoroughly with potable water.

For sprayer applications, use a coarse spray device. Spray 6-8 inches from the surface, rub with a brush, sponge, or cloth. Do not breathe spray.

For use on non-food contact surfaces as a general disinfectant in the brewery industry, use 400 to 800 ppm active quaternary. Follow disinfectant directions above.

DISINFECTING – POTATO STORAGE AREA AND EQUIPMENT

Remove all potatoes prior to disinfection of potato storage area or equipment. Preclean hard surfaces by removing heavy soil or gross filth. Follow general disinfection (1 oz per 2 gal.) procedures as outlined above. All treated surfaces must be thoroughly rinsed with potable water prior to reuse.

DISINFECTION OF BARBER AND BEAUTY SHOP INSTRUMENTS AND TOOLS

Thoroughly pre-clean. Completely immerse brushes, combs, scissors, clipper blades, razors, tweezers, manicure and other shop tools for 10 minutes (or as required by local authorities) with 1 oz. **Ster-Bac** to 2 gal. water (400 ppm). Fresh solution must be prepared daily, or more often if the solution becomes diluted or soiled. After disinfection, wipe dry the product as appropriate. NOTE: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

DISINFECTION – NON-FOOD CONTACT SURFACES

Pre-clean surfaces. Disinfect waterproof work boots, tools, forklifts, and hand trucks with 1 oz. **Ster-Bac** diluted in 1 to 2 gal. water (400 - 800 ppm active quaternary). For waterproof boots and tools, thoroughly apply use solution by immersion, foam, or coarse spray. For forklifts and hand trucks, thoroughly apply by coarse spray and foam. Treated surfaces must remain wet for 10 minutes. Allow to air dry.

SELF-SANITIZING COATING AND SPRAY DISINFECTION

Surfaces must be free of dust, soil and greases. Clean with an appropriate detergent and rinse with water prior to application if necessary.

Use a high quality spray system equipped with a mixing spray gun. The Ecolab Food and Beverage representative will make equipment recommendations. Wear appropriate protective equipment to minimize inhalation and eye/skin contact.

Fill one reservoir with undiluted **Ster-Bac**. Fill the other reservoir with undiluted **KX-6033**. Connect the reservoirs to the spray equipment and purge all air from the spray lines. Calibrate the spray equipment to deliver equal volumes of **KX-6033** and **Ster-Bac**. Adjust to a fine mist. Use overlapping strokes to coat the entire surface to be treated.

Typical coverage is 4,000-5,000 square feet per gallon of **Ster-Bac**.

SPRAY DISINFECTING

Disinfect previously cleaned hard non-porous surfaces following general application procedures described above. Product must remain in contact with surface for 10 minutes. Allow coating to dry.

RESIDUAL SELF-SANITIZING

After the product has been applied to non-food contact surfaces as described above and the coating allowed to dry, the surfaces can be sanitized by wetting with a spray of cool water. The surface must remain moist for 5 minutes. Duration of residual self-sanitizing is dependent upon surface exposure conditions. Avoid manual scrubbing or abrasion of the coated surfaces and acidic cleaning products since these will remove the coating. For continuous self-sanitizing activity, reapply within 60 days.

REMOVAL

Coatings can be removed from surfaces with mildly acidic detergents such as **AC-3** (supplemented with **Klenz-Foam**) or **Foam-Shine**. Manual scrubbing and abrasion will also result in the removal of the coating.

SANITIZING – NON-POROUS GLOVED HANDS: To prevent cross-contamination into animal areas and the packaging and storage areas of food plants, dip pre-washed (plastic, latex or other synthetic rubber) gloved hands into a suitable clean container that contains enough freshly made sanitizing solution to cover the gloved area. **Do not let sanitizing solution come into contact with the exposed skin.** Make up the sanitizing solution by adding 1 oz product in 3 gal. of water (250 ppm active) up to 1 oz product in 2 gal water (400 ppm active) (or equivalent use dilution). Dip (soak) in solution for 60 seconds. **POTABLE WATER RINSE IS ALLOWED.** Change the sanitizing solution in the bath at least daily or when solution appears dirty.

SANITIZING EQUIPMENT - FOOD PROCESSING PLANTS – RESTAURANTS

For sanitization of equipment in food processing plants, restaurants, remove gross food particles and excess soil by a pre-flush or pre-scrape, wash with a good detergent or compatible cleaner, rinse equipment thoroughly with clear water, then rinse equipment with a sanitizing solution of 1 oz product in 3 gal. of water (250 ppm active) up to 1 oz product in 2 gal water (400 ppm active) (or equivalent use dilution). All surfaces must be exposed to the sanitizing solution for a period of not less than 1 minute. Allow equipment to drain thoroughly and air dry. **Ster-Bac** is an effective food contact surface sanitizer against *Escherichia coli* (ATCC 11229), *Staphylococcus aureus* (ATCC 6538), *Listeria monocytogenes* (ATCC 49594) and *Enterobacter sakazakii* (ATCC 12868).

ENTRYWAY SANITIZING SYSTEMS

To prevent cross contamination from area to area, set the system to deliver sanitizing solution at 0.5 – 1.5 oz. product per gallon of water (or equivalent use dilution) (400-1200 ppm active quat). The foam (or spray) should cover the entire path of the doorway. Set the system so that a continuous wet blanket of sanitizer solution is delivered to the floor. Do not mix other foam additives to the sanitizing solution.

SHOE BATH SANITIZER DIRECTIONS

To prevent cross-contamination into animal areas, shoe baths containing one inch of freshly made solution should be placed at all entrances to buildings and hatcheries. Sanitize in a solution of 1 oz product in 3 gal. of water (250 ppm active) up to 1 oz product in 2 gal water (400 ppm active) (or equivalent use dilution). Scrape waterproof work boots (shoes) and place in solution for 60 seconds prior to entering area. Change the solution in the bath daily or sooner if solution appears diluted or soiled.

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SHOE FOAM SANITIZER DIRECTIONS

Ster-Bac can be used to prevent cross-contamination into animal areas and packaging and storage areas of food plants. Apply a foam layer approximately 0.5 to 2 inches thick made from a solution of 1 to 1.5 ounces product per gallon of water (or equivalent use dilution) (800 to 1200 ppm active) at all entrances to buildings, hatcheries, production and packaging rooms by using a foam generating machine or aerator to apply foam layer. Follow the foaming directions as specified by the manufacturer of the foam generator/aerator. Scrape waterproof shoes. Stand and/or walk through foamed area for 60 seconds prior to entering area. Foam area must be washed and replaced daily or when it appears dirty.

ELEVATED TEMPERATURE SANITIZING

For sanitization of equipment in food processing plants, restaurants, remove gross food particles and excess soil by a pre-flush or pre-scrape, wash with a good detergent or compatible cleaner, rinse equipment thoroughly with clear water, then rinse equipment with a sanitizing solution. At a temperature of 120 deg F, this product is an effective sanitizer for food contact surfaces at 1 ounce product to 10 gallons of water. All surfaces must be exposed to the sanitizing solution for a period of not less than 1 minute. Allow equipment to drain thoroughly.

SANITIZING EATING AND DRINKING UTENSILS

1. Scrape and preflush utensils to remove excess soil.
2. Wash with good detergent or compatible cleaner (see your Ecolab representative for a recommendation).
3. Rinse with clear water.
4. Sanitize in a solution of 1 oz product in 3 gal. of water (250 ppm active) up to 1 oz product in 2 gal water (400 ppm active) (or equivalent use dilution). Immerse all utensils for at least one minute. Use 2 minutes exposure time if required by governing sanitary code.
5. Drain and air dry.

NOTE:

FOR MECHANICAL OPERATIONS prepared use solution may not be reused for sanitizing but may be reused for other purposes such as cleaning.

FOR MANUAL OPERATIONS fresh sanitizing solution should be prepared as soon as they become diluted or soiled.

Ster-Bac fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinance 1978. Recommendation of the U.S. Public Health Service in water up to 500 ppm of hardness calculated as CaCO₃ when tested by the A.O.A.C Germicidal and Detergent Sanitizer Official Method.

FOR CONTINUOUS TREATMENT OF MEAT AND POULTRY OR FRUIT AND VEGETABLE CONVEYORS

Remove gross food particles and excess soil by a pre-flush or pre-scrape, wash with a good detergent or compatible cleaner, rinse equipment thoroughly with clear water, then rinse equipment with a sanitizing solution. During processing, apply **Ster-Bac** at a 250-400 ppm quat level to conveyors with MIKRO MASTER or other suitable feeding equipment. Controlled volumes of sanitizer are applied to return portion of conveyor through nozzles so located as to permit maximum drainage of sanitizer from equipment and to prevent puddles on top of belt. During interruptions in operation, coarse spray equipment, peelers, collators, slicers and saws with MIKRO MASTER dispensed **Ster-Bac** solution of 250-400 ppm quat. Conveyor equipment should be free of product when applying this coarse spray.

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SANITIZING SHELL EGGS INTENDED FOR FOOD

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants, spray with a solution of 1 oz product in 3 gal. of warm water up to 1 oz product in 2 gal of warm water (250-400 quat). The solution should be warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product shall be subjected to a potable water rinse only if they are broken immediately for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. The solution must not be reused for sanitizing eggs.

Note: Only clean, whole eggs can be used for sanitizing. Dirty, cracked, or punctured eggs cannot be sanitized.

FOR CONTROL OF SMALL FLIES ON SURFACES

For control of small flies: *Drosophila spp.* and the Phoridae family. To control flies on non-food contact surfaces such as floors, walls, countertops, metal surfaces, painted surfaces, glazed porcelain, glazed tile, glass, chrome, rubber, and plastic in restaurants, kitchens, dishwashing areas, and bar and wait stations areas. Remove food and food packaging prior to use. Cover exposed food-handling surfaces. After removing gross filth, apply a solution of 1 oz Ster-Bac to 1 gal. of water (800 ppm) to surfaces and locations where flies may breed. Spray surfaces thoroughly or apply by pouring, mopping or sponging onto the surface. Repeat application 1-2 times per week or as needed. Do not contaminate food or food packaging.

FOR CONTROL OF SMALL FLIES IN DRAINS

For control of small flies: *Drosophila spp.* and the Phoridae family. Spray or Pour 1 gallon of Ster-Bac finished solution, 1 oz. to 1 gal. of water (800 ppm), into drain during time of lowest level of drain use. Add 4 ounces daily of Ster-Bac concentrate to each drain to maintain fly control. Apply around the edge of the drain and coat all sides of inside of drain.

ALGAE AND SLIME CONTROL IN COOLING AND PROCESS WATERS

Ster-Bac is formulated to provide control of growth of algae and slime in recirculating cooling water systems and evaporative condensers as well as cooling tunnels and warmers. It can be used in cooling water for thermal processing and pasteurizing operations in dairies, breweries, soft drink and food canning plants.

To control algae and bacterial slimes, use as directed. For best results, slug feed. Add directly from the product container using proper and accurate dispensing equipment. The frequency of addition needed depends on many factors. To optimize your use, follow this procedure:

Recirculating Cooling Towers and Other Process Waters

Initially use not more than 25 fluid ounces per 1,000 gallons of water to be treated (up to 20 ppm active quaternary). Increase dosage to 45 fluid ounces per 1,000 gallons of water, if necessary, except in dairy recirculating cooling water (commonly referred to as sweetwater) systems where dose is limited to not more than 20 ppm actives. Repeat initial dose every seven days or increase the frequency, if needed.

Staining and Corrosion Control in Federally Inspected Meat and Poultry Plants

May be added to water of sealed containers of meat and poultry products to prevent staining, corrosion, or deposit formation on containers and processing equipment. This product must be used at the same application rates, and in the same manner as described above for recirculating cooling tower water.

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STORAGE & DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.

PESTICIDE STORAGE: Store this product in a cool, dry area, away from direct sunlight and heat.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:

(≤ 5-gallons rigid) Nonrefillable container. Do not refill or reuse container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

(>5-55-gallons rigid) Nonrefillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

(≤2.5 gal bladder in box) Nonrefillable container. Do not reuse or refill this container. Remove empty bladder from outer corrugated box. Triple rinse bladder (or equivalent). Offer box and bladder for recycling, if available.

(Totes) Verify that the tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

- Net Contents: 1 gallon (3.78 l)
- 2.5 gallon (9.45 l)
- 5 gallons (18.9 l)
- 55 gallons (208.8 l)
- 350 gallon tote

EPA Reg. No. 1677-43
 EPA Est.: 303-IN-1 (L), 1677-MN-1 (P)
 1677-CA-2 (R), 1677-TX-1 (D),
 1677-IL-2 (J), 1677-CA-1 (S)
 1677-GA-1 (M), 1677-WV-1 (V)
 Superscript refers to first letter of date code

Ecolab Inc.
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