

1677-43

8/31/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 31 2004

Brian C. Brosdahl
Senior Manager, Regulatory Affairs
Ecolab Inc.
370 N. Wabash Street
St. Paul, MN 55102

Subject: **Ster-Bac**
EPA Registration Number 1677-43
Application Dated June 4, 2004
EPA Received Date June 8, 2004

Dear Mr. Brosdahl:

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

Proposed Amendment:

- add "Hand Sanitizing" directions for use

Label Comments:

1. Revise the "Sanitizing-Non-Porous Gloved Hands" as follows:
 - a. Since your product is cleared as a food contact sanitizer we will allow the gloves to be sanitized prior to use in packaging and storage areas of food plants.
 - b. we are very concerned about personnel exposing their hands to the sanitizing solution, thus place the following statement in bold text: "Do not let sanitizing solution come into contact with exposed skin."
2. Revise the "Sanitizing-Non Porous Gloved Hands" directions to read exactly as follows, deleting all of your proposed text.

To prevent the spreading of harmful organisms into animals areas and the packaging and storage areas of food plants, dip per-washed (plastic, latex or other synthetic rubber) gloved hands into a suitable clean container that contains enough freshly made

CONCURRENCES


SYMBOL							
SURNAME							
DATE							

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 a 1ounce of this product per 4 gallons of water (or equivalent use dilution) (200 ppm active). Dip (soak) in solution for 60 seconds. **No POTABLE WATER RINSE IS ALLOWED.** Change the sanitizing solution in the bath at least daily or when solution appears dirty.

General Comments:

A stamped copy of the labeling accepted with conditions is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland on (703) 308-6224.

Sincerely,

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

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STER-BAC

QUATERNARY AMMONIUM SANITIZER - DISINFECTANT - DEODORIZER

ACTIVE QUATERNARY

INSTITUTIONS - HOSPITALS - NURSING HOMES - 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%

INERT 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. 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): 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.

**FOR INSTITUTIONAL AND COMMERCIAL USE ONLY
DO NOT MIX WITH ANYTHING BUT WATER**

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

AUG 31 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1677-43

DIRECTIONS FOR USE

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

DEODORIZING

After cleaning, deodorize waste containers and inaccessible areas in food processing plants with 1 oz **Ster-Bac** to 1 gal. of water (800 ppm). Flush surfaces thoroughly or apply by mopping or sponging onto the surface.

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 porous surfaces such as ceiling boards, chopping blocks, pallets, rubber conveyor belts and 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.

Fogging can be used as an adjunct to acceptable manual cleaning and disinfecting as described above. Prior to fogging, food products and packaging material must be removed from the room or carefully protected. After cleaning, fog desired areas using one quart per 1000 cu. Ft. of room area with a **Ster-Bac** solution containing 1.5 oz of product to 1 gallon (1200 ppm). Vacate the area of all personnel for a minimum of 2 hours after fogging. All food contact surfaces must be sanitized with a **Ster-Bac** solution of 200 ppm active quaternary (1/2 oz per 2 gal.) prior to reuse. Allow food contact surfaces to drain thoroughly before operations are resumed.

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 should 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: Use **Ster-Bac** solution at 200 ppm (1 oz. per 4 gallons of water) active quaternary to sanitize gloved hands. The gloved hands need not be rinsed after use of **Ster-Bac**.

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 to 4 gal. of water (200 ppm). All surfaces should 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 *Listeria monocytogenes*.

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 should 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 ½ oz product to 2 gallons of water (200 ppm). (Alternate directions: Sanitize in a solution of 1 oz product to 4 gallons of water.) 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 200 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 200 ppm quat. Conveyor equipment should be free of product when applying this coarse spray.

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 4 gal. of warm water (200 ppm 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 should be reasonably dry before casing or breaking. The solution should 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 should be used at the same application rates, and in the same manner as described above for recirculating cooling tower water.

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 DISPOSAL:

(1 gal. or 2 L) - Do not reuse container. Wrap container and put in trash.

(5 gal., 55 gal.) - Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(1 gal. bladder in box) Remove empty bladder from outer corrugated box. Do not reuse bladder. Wrap bladder and box and put in trash.

(2.5 gal. bladder in box) Remove empty bladder from outer corrugated box. Triple rinse bladder (or equivalent). Offer box and bladder for recycling or dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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

(Reusable container statement) Container can be reused once the container is empty. Empty container of concentrate into dilution dispenser [specific equipment such as "Simplex dispenser" can be named to replace "dilution dispenser".] Dispenser will automatically dilute a sanitizer [or disinfectant] solution.

Remove concentrate label. Refill container with use dilution of concentrate from the dispenser. Replace cap with spray nozzle provided. Place correct use dilution label on the spray bottle.

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-OH-1 (H)

Ster-Bac label

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Ecolab Inc.
370 North Wabasha Street
St. Paul, MN 55102-1390

1677-IL-2 (J), 1677-PR-1 (B), 1677-CA-1 (S)
1677-NJ-1 (W), 1677-GA-1 (M), 1677-WV-1 (V)
Superscript refers to first letter of date code