

(2-2-1994)

1

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 1

Date RD Received: 3 November 93 Review Start Date: 18 Nov 93

Date EPA Received: 15 October 93

Project Return Date: 2 Feb 94 Review Completion Date: 18 Nov 93

Reviewed by: Michelle E. Wingfield Date: 18 November 93

EPA Reg. No. or File Symbol: 1677-43

EPA Petition or EUP No.: None

Product Type: Hospital Disinfectant/Food Contact Surface Sanitizer

MRID No(s): 429694-01

Product Manager & Team No.: John Lee-31

Product Name: Ster-Bac

Company Name: Ecolab Inc.

Submission Purpose: An amendment to include label directions for sanitizing at elevated temperatures.

Product Formulation: A liquid concentrate to be diluted for use.

ACTIVE INGREDIENT(S)

n-Alkyl (C14 50%, C12 40%, C16 10%) dimethyl
benzylammonium chloride

10.0

200.0 **INTRODUCTION**

200.1 **USE(S):** The proposed product, Ster-Bac EPA Reg. # 1677-43, is a hospital disinfectant/food contact surface sanitizer. Refer to the attached label for specific uses.

200.2 **BACKGROUND INFORMATION:** The submission is a label amendment with confirmatory data in support of elevated temperature sanitizing.

201.0 **DATA SUMMARY**

201.1 **BRIEF DESCRIPTION OF TESTS:**
 MRID# 429694-01
 Germicidal and Detergent Sanitizer Test, Official Final Action, A.O.A.C. Methods of Analysis 15th Edition, 1990.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 2

EPA Registration No.: 1677-43

Date EPA Received: 15 October 93

Date RD Received: 3 November 93

Project Return Date: 2 February 94

Review Start Date: 18 November 93

Review Completion Date: 18 November 93

MRID No(s): 429694-01

Product Manager & Team No.: John Lee-31

Product Name: Ster-BAC

Company Name: Ecolab Inc.

202.0 **RECOMMENDATIONS**

202.1 **EFFICACY SUPPORTED BY THE DATA:**

The submitted Confirmatory Data supports the effectiveness of the product as a sanitizer against Staphylococcus aureus and Escherichia coli, when diluted 1 ounce per 10 gallons of hard water (500 ppm as CaCO₃) when used on previously cleaned food contact surfaces for a contact period of not less than 1 minute at a temperature of 130 degrees farenheit.

203.0 **LABELING**

a. The highlighted areas on pages 2 and 3 are acceptable.

STER-BAC

QUATERNARY AMMONIUM SANITIZER - DISINFECTANT - DEODORIZER

ACTIVE INGREDIENT:

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

INERT INGREDIENTS: 90.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS - HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes severe eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Wear rubber gloves, chemical goggles and protective clothing when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Avoid contamination of food.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush immediately with cool water. Remove contact lenses. Continue flushing for 15 minutes, holding eyelids apart. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF SWALLOWED: Rinse mouth at once; then drink one or two glasses of water. DO NOT INDUCE VOMITING. Never give anything by mouth to an unconscious person.

CALL A POISON CONTROL CENTER OR PHYSICIAN IMMEDIATELY

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

FOR INDUSTRIAL USE ONLY

DO NOT MIX WITH ANYTHING BUT WATER

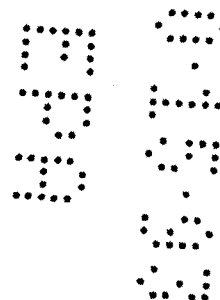
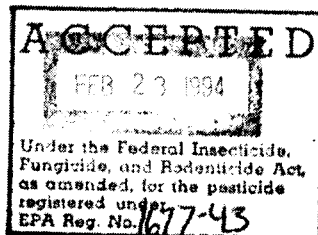
Net Contents: 1 gallon (3.78 l)
2.5 gallons (9.45 l)
5 gallons (18.9 l)
55 gallons (208.8 l)

EPA Reg. No. 1677-43

EPA Est. 1677-IL-2 (J), 1677-NJ-1 (W), 1677-TX-1 (D), 1677-GA-1 (M), 1677-MN-1 (P), 1677-~~GA~~ (S),
1677-PR-1 (B)

The superscript refers to the first letter of the date code.

Ecolab Inc.
Ecolab Center
St. Paul, MN 55102



**INSTITUTIONS - HOSPITALS - NURSING HOMES - SCHOOLS - RESTAURANTS -
FOOD SERVICES - DAIRIES - BEVERAGE AND FOOD PROCESSING PLANTS****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 gl of water (800 ppm). Flush surfaces thoroughly or apply by mopping or sponging onto the surface.

DISINFECTING - Disinfect previously cleaned hard surfaces such as walls, floors, woodwork, sinks, bathroom fixtures, with 1 oz **Ster-Bac** to 2 gl of water (400 ppm). For disinfecting previously cleaned porous surfaces such as ceiling board, chopping blocks, pallets, rubber conveyor belts, in meat, poultry and other food processing operations, use 1 oz **Ster-Bac** to 1 gl (800 ppm). Flush surfaces thoroughly or apply by mopping sponging or course spraying on surface. All surfaces should be exposed to the disinfecting solution for a period of not less than 10 minutes. Food contact surfaces which have been disinfected must be rinsed thoroughly with potable water.

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.

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 **Ster-Bac** to 1 gl (1200 ppm). Vacate the area of all personnel for a minimum of 2 hours after fogging. All food contact surfaces must be thoroughly rinsed with a **Ster-Bac** solution of 200 ppm active quaternary (1/2 oz per 2 gl) prior to reuse. Allow food contact surfaces to drain thoroughly before operations are resumed.

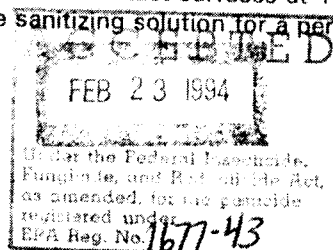
DISINFECTING - POTATO STORAGE AREA AND EQUIPMENT - Remove all potatoes prior to disinfection of potato storage area or equipment. Preclean hard surfaces by removing heavy soil or gross filth. Follow general disinfection (1 oz per 2 gl) procedures as outlined above. All treated surfaces must be thoroughly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

SELF-SANITIZING COATING AND SPRAY DISINFECTION
(insert from attached - long or short form)

SANITIZING EQUIPMENT - FOOD PROCESSING PLANTS - RESTAURANTS - ETC. - For sanitization of equipment in food processing plants, restaurants, etc., 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 **Ster-Bac** to 4 gallons 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.

ELEVATED TEMPERATURE SANITIZING

For sanitization of equipment in food processing plants, restaurants, etc., 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 130 deg F, **Ster-Bac** is an effective sanitizer for food contact surfaces at 1 ounce **Ster-Bac** 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 1/2 oz **Ster-Bac** to 2 gallons of water (200 ppm). (Alternate directions: Sanitize in a solution of 1 oz **Ster-Bac** 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 waters up to 500 ppm of hardness calculated as CaCO_3 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 gl of warm water (200 ppm quat). The solution should be warmer than the eggs, but not to exceed 130 deg 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.

For service or additional information, call 1-800-35-CLEAN (352-5326).

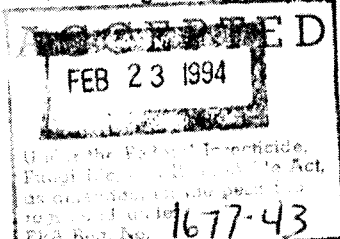
STORAGE & DISPOSAL

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

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 gl) Do not reuse empty containers. Wrap container and put in trash. (5, 55 gl plastic) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(2.5 gl 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.



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Ster-Bac Label Modification - Under Directions for Use.**SELF-SANITIZING COATING AND SPRAY DISINFECTION (Short Form)**

Using appropriate equipment, **Ster-Bac** can be applied together with Klenzade KX-6033 to yield a coating that disinfects the surface upon initial application and subsequently provides a residual self-sanitizing coating. See Technical Bulletin for complete directions for application and use.

SELF-SANITIZING COATING AND SPRAY DISINFECTION (Long Form)

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 Klenzade representative will make equipment recommendations. Wear appropriate protective equipment to minimize inhalation and eye/skin contact.

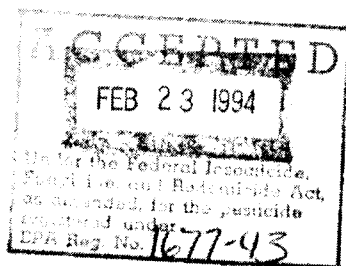
Fill one reservoir with undiluted **Ster-Bac**. Fill the other reservoir with undiluted **KX-6033**. Connect the reservoirs to the spray equipment and purge all air from the spray lines. Calibrate the spray equipment to deliver equal volumes of **KX-6033** and of **Ster-Bac**. Adjust to a fine mist. 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 would 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 Klenzade **AC-3** (supplemented with **Klenz-Foam**) or **Foam-Shine**. Manual scrubbing and abrasion will also result in the removal of the coating.



Signature
01/16/94

