

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

ANTIMICROBIAL PROGRAM BRANCH

IN 07/16/90 OUT 08/09/90

Reviewed by Srinivas Gowda Date 8/14/90 08/09/90

EPA Reg. No. or File Symbol 1677-43

EPA Petition or EUP No. None

Date Division Received 06-07-90

Type Product (s): Hospital Disinfectant/

Food Contact Surface Sanitizer

MRID No(s) 415473-01

Product Manager PM 31 (Lee)

Product Name Ster-Bac

Company Name Ecolab Inc., Ecolab Center

Submission Purpose Amendment to additinal claim as residual
self-sanitizer and use directions as spray
disinfectant with efficacy data and proposed
labels (attached)

Type Formulation Liquid to be used diluted

Active Ingredient (s): 3

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

200.0 **Introduction**

200.1 **Uses (s)**

Refer to the proposed labeling dated 07-02-90.

200.2 **Background Information**

The submission received 06-07-90, is an amendment to add residual self-sanitizing activity claims for hard, inanimate environmental surfaces and use directions as spray disinfectant with efficacy data and proposed labeling.

201.0 **Data Summary**

201.1 **Brief Description of Tests**

"Ster-Bac (with Coating Adjuvant) Self-sanitizing Activity" by Thomas G. Boufford, Ecolab Inc., 840 Sibley Memorial Highway, Mendota Heights, MN 55118, dated 03-09-90 (MRID No. 415473-01).

201.2 **Test Summaries:**

Sanitizer Test (Residual Self-Sanitizing Activity Test for inanimate non-food contact surfaces)

- a. The submitted protocol for the evaluation of residual self-sanitizing activity was previously reviewed and accepted by EETMS, APB, RD, for this product on 06-14-88 and 09-01-89.

The methodology employed and test results are attached.

- b. Satisfactory performance vs. test organisms.

A0BAC

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Pages 3 through 21 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
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- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☒ FIFRA registration data.
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- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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%

PRECAUTIONARY STATEMENTS - HAZARDS TO HUMANS AND DOMESTIC ANIMALS

KEEP OUT OF REACH OF CHILDREN

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

PELIGRO: SI NO PUEDE LEER EN INGLES PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

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: Drink promptly large quantities 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)
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-CA-1 (S), 1677-PR-1 (B), 6574-CA-1 (L)

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

Klenzade, Division of 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 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 are disinfected, must be thoroughly rinsed with potable water or a sanitizing solution of Ster-Bac (1/2 oz per 2 gl) prior to reuse. Allow food contact surfaces to drain thoroughly and air dry before operations are resumed.

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 potable water or a Ster-Bac solution of 200 ppm active quaternary (1/2 oz per 2 gl) prior to reuse. Allow food contact surfaces to drain and air dry before operations are resumed.

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

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.

SANITIZING EQUIPMENT - FOOD PROCESSING PLANTS - RESTAURANTS - ETC.

For sanitization of equipment in food processing plants, restaurants, etc., clean and rinse equipment thoroughly. Then rinse equipment with a sanitizing solution of 1 oz Ster-Bac to 4 gl (200 ppm). All surfaces should be exposed to the sanitizing solution for a period of not less than 1 minute. Allow equipment to air dry.

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 gl (200 ppm). 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.

OTHER USES: For other specialized cleaning and disinfecting operation consult your Ecolab Specialist.

LOCAL AND STATE REGULATIONS

Where local or state regulations are in effect concerning quaternary compounds, consult them for recommended dilutions and procedures.

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 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.



Division of Ecolab Inc.
STER-BAC (EPA REGISTRATION NO. 1677-43)
NEW USE AMENDMENT

Label Modification (Short Form) - Under Directions for Use.

SELF-SANITIZING COATING

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.





**STER-BAC (EPA REGISTRATION NO. 1677-43)
NEW USE AMENDMENT**

**MASTER LABEL MODIFICATION
INSTITUTIONS - HOSPITAL - NURSING HOMES - SCHOOLS
RESTAURANTS - FOOD SERVICES - DAIRIES - BEVERAGE
FOOD PROCESSING PLANTS**

SELF-SANITIZING COATING & 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 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 ten 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 five 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.



TECHNICAL BULLETIN

STER-BAC BASED SPRAY DISINFECTANT AND SELF-SANITIZING COATINGS FOR NON-FOOD CONTACT SURFACES

THE PROBLEM

Dairy, beverage and food processing plant operators and institutional establishments want to improve the level of sanitation of environmental surfaces within their facilities. However, these large surfaces with difficult to reach areas hinder effective implementation of complete daily environmental sanitation programs. At existing production staffing levels within plants, there simply may not be enough time and manpower to effectively clean and sanitize both production equipment and environmental surfaces. As a result, the environmental surfaces are often neglected.

When environmental sanitation is performed, quaternary ammonium sanitizers are typically used because they leave residual antimicrobial on the surface. However, the quaternary ammonium compound is very water soluble and is easily rinsed from the surface after minimal incidental water contact, leaving little residual antimicrobial activity.

Dairy beverage and food processing plant operators and institutional establishments need an antimicrobial product that maintains its residual antimicrobial activity for a period ranging from weeks to months after a single application despite incidental water contact.

THE SOLUTION

Using STER-BAC as the antimicrobial agent, Klenzade has developed a process that meets this need. In this unique and proprietary system STER-BAC is mixed during spray application with a reactive polymer, KX-6033, to form a largely water insoluble quat-polymer coating on the surface. Upon initial application of the product, the treated surface will be disinfected. Repetitive wettings with water slowly dissolve some of the coating each time to release enough quaternary ammonium antimicrobial to sanitize the coated surface.

Results presented in Table 1 compare the residual antimicrobial activity of the STER-BAC based self-sanitizing coating with that obtained using 400 ppm of STER-BAC alone. In this experiment, the STER-BAC based self-sanitizing coating was applied to one surface and a 400 ppm solution of STER-BAC (in deionized water) was applied to another. Both surfaces were allowed to dry and were then exposed to sequential, five minute low pressure water rinses. After each rinse, the surfaces were allowed to dry and then were subjected to a microbial challenge, Staphylococcus aureus, ATCC 6538. Log reductions in bacterial count due to exposure to these treatments are presented in Table 1.

TABLE 1

Surface Treatment	Exposure (minutes)	Log Reductions After Water Exposure				
		0	5	10	25	75
STER-BAC Coating		>6.0	>6.0	>6.0	5.8	5.5
STER-BAC Solution		>6.0	0.3	0.0	0.0	0.0

The laboratory results demonstrate that the effective sanitizing residual of the STER-BAC coating remains after exposure to greater than 60 minutes of water spray while a 400 ppm quat residue of STER-BAC alone is rinsed away.

Similar results have been observed during extensive field testing of the STER-BAC based antimicrobial coating - a process that redefines the performance expectations of residual sanitizing.

DIRECTIONS FOR APPLYING THE STER-BAC SELF-SANITIZING COATING

Use a high quality spray system equipped with a mixing spray gun. Satisfactory results have been obtained with an Ecolab dual spray system using a mixing spray gun with a fan spray tip.

Wear appropriate protective equipment to minimize inhalation and eye/skin contact.

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

Add one gallon of undiluted STER-BAC to one reservoir of the sprayer. 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 (it is critical that equal volumes of each component are delivered). Adjust to a fine mist. Use overlapping strokes to coat the entire surface to be treated. Allow to dry.

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 ten minutes. Allow coating to dry.

RESIDUAL SELF-SANITIZING

After the product has been applied to non-food contact surfaces as described above and allowed to dry, the surface can be sanitized by wetting with a spray of cool water. The surface must remain moist for five minutes. For surfaces routinely exposed to incidental water contact, routine spray is not required. Avoid manual scrubbing or abrasion of the coated surfaces and acidic cleaning products since these would remove the coating.

Duration of residual self-sanitizing is dependent upon surface exposure conditions. Routine reapplication over an existing coating is possible. 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.

EPA Registration No. 1677-43.

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Rev. 5/90

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Pages _____ through _____ are not included in this copy.

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EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-II

ANTIMICROBIAL PROGRAM BRANCH

EPA Reg. No. or File Symbol 1677-43
Date Division Received 06-07-90
MRID No(s) 415473-01
Product Manager PM 31 (Lee)
Product Name Ster-Bac
Company Name Ecolab Inc., Ecolab Center

202.0 Recommendations

202.1 Efficacy Supported By the Data

The submitted data developed by the Sanitizer Test (for inanimate non-food contact surfaces) are acceptable to demonstrate residual self-sanitizing activity ($\geq 99.9\%$ reduction) of the 1:1 Ster-Bac Adjuvant KX6033 coated hard surface against Staphylococcus aureus ATCC 6538 and Klebsiella pneumoniae ATCC 4358 in the presence of 5% blood serum for up to and including 60 cycles of 5 minute water exposure at $21^{\circ}\text{C} \pm 1^{\circ}\text{C}$ at 5 minute contact time where abrasion is not likely.

203.0 Labeling

Identify the type of non-food contact surfaces intended for self-sanitizing coating.

Self Sanitizing
review