TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 03-09-88 Out 06-14-88

Srinivas Gowda WEC 6-20-88

Reviewed By Srinivas Gowda Date 06-14-88

EPA Reg. No. or File Symbol 1677-43

EPA Petition or EUP NO. None

Date Division Received 01-12-88

Type Product Disinfectant/Food Contact Surface Sanitizer

Data Accession No. 404704-01 & 404704-02

Product Manager 31 (Lee)

Product Name STER-BAC® Quaternary Ammonium/Sanitizer

Company Name Klenzade, Division of Ecolab Inc.

Submission Purpose Amendment to add residual self-sanitizing activity claims for hard, inanimate environmental surfaces; new pattern of use i.e., spray disinfecting hard, inanimate surfaces with coating Adjuvant; potato storage area and equipment disinfection claims to the label with efficacy data and proposed label. Also, response to LIP notice for Food Contact Surface Sanitizers.

Type Formulation Liquid to be used diluted/Liquid to be used with coating adjuvant

Active Ingredient(s):

	%
(n-Alkyl[50% C_{14}, 40% C_{12}, 10% C_{16}]dimethyl benzyl ammonium chloride)	10.0

(1)

200.0 Introduction

200.1 Use(s)

See attached proposed label

200.2 Background Information

The submission received 01-12-88, is an amendment to add residual selfsanitizing activity claims for hard, inanimate environmental surfaces; new pattern of use i.e., spray disinfecting hard, inanimate surfaces with coating Adjuvant; potato storage area and equipment disinfection claims to the label with efficacy data and proposed label. Also, response to LIP notice for Food Contact Surface Sanitizers.

201.0 Data Summary

201.1 Brief Description of Test

"Ster-Bac Residual Self-Sanitizing Activity"by Thomas G.Boufford, Ecolab Inc.,840 Sibley Memorial Highway, Mendota Heights, MN 55118, dated 10-26-87 (MRID No. 404704-01).

"Ster-Bac - Spray Disinfectant (With Coating Adjuvant" by Thomas G. Boufford, Ecolab Inc.,840 Sibley Memorial Highway, Mendota Heights, MN 55118, dated 11-25-87 (MRID No. 404704-02).

201.2 Test Results

a. Bactericidal Test

1. The methodology employed and test results are attached.

2. Conclusions: Satisfactory performace vs test orgamnisms.

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

1. The methodology employed and test results are attached.

2. Conclusions: The submitted data are inadequate. See 202.2.

KLENZADE®

EPA Reg. No. 1677-43 EPA Est. No. 1677-IL-2

STER-BAC®

Quaternary Ammonium Sanitizer

ACTIVE INGREDIENTS:	
(n-Alkyl [50% C_{14}, 40% C_{12}, 10% C_{16}] dimethyl benzyl ammonium chloride)	10.0%
INERT INGREDIENTS:	90.0%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panel for first aid instructions and additional precautions

Manufactured by: KLENZADE, Division of Ecolab Inc., Ecolab Center St. Paul, MN 55102, ®, 1987

NET CONTENTS:

1 U.S. GAL. (3.78 l)

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a 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 gallon of water (800 ppm). Flush surfaces thoroughly or apply by mopping or sponging onto the surface. All surfaces should be exposed to the sanitizing solution for a period of not less than 1 minute.

DISINFECTING

Disinfect previously cleaned hard surfaces such as walls, floors, woodwork, sinks, bathroom fixtures, with 1 oz. of Ster-Bac to 2 gallons 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 gallon of water (800 ppm). Flush surfaces thoroughly. ~~All surfaces should be exposed to the sanitizing solution for a period of not less than 1 minute.~~ Food contact surfaces which are disinfected, must be thoroughly rinsed with potable water prior to reuse.

(1) → Fogging can be used as an adjunct to acceptable manual cleaning and disinfecting as described above. Prior to fogging as an adjunct to acceptable manual cleaning and disinfecting, food products and packaging materials must be removed from the room or carefully protected. Fog desired areas using one quart per 1000 cu. ft. of room area with a Ster-Bac solution containing 15 oz. of Ster-Bac to 1 gallon of water providing 1,700 ppm active quaternary. Vacate the area of all personnel for a minimum of 2 hours after fogging. All food contact surfaces must then be thoroughly rinsed with potable water or a Ster-Bac solution of 200 ppm active quaternary. Allow surfaces to dram thoroughly before operations are resumed.

SANITIZING EQUIPMENT — FOOD PROCESSING PLANTS

For sanitation of equipment in food processing plants, clean and rinse equipment thoroughly. Then rinse equipment with 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 air dry.

SANITIZING EATING AND DRINKING UTENSILS

1. Scrape and prefluish 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. Ster-Bac to 2 gallons of water (200 ppm). Immerse all utensils for at least two minutes.
5. Drain and air dry.

GUARANTEED PHENOL COEFFICIENT AT 20°

Staphylococcus aureus	75
Salmonella typhosa	50

NOTE: FOR MECHANICAL OPERATIONS prepared use solutions may not be re-used for sanitizing but may be re-used for other purposes such as cleaning.

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

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Causes severe eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Avoid contamination of foods.

ENVIRONMENTAL HAZARDS:

This product is toxic to fish. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. 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.

FIRST AID

EXTERNAL: Immediately flush skin with plenty of water. Remove and wash contaminated clothing.

EYES: Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.

INTERNAL: If swallowed, immediately drink a large quantity of milk, egg whites or gelatin solution. If these are not available, drink large quantities of water.

GET MEDICAL ATTENTION IMMEDIATELY

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

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. Recommendations of the U.S. Public Health Service in waters up to 550 ppm of hardness calculated as $CaCO_3$ when tested by the A.O.A.C. Germicidal and Detergent Sanitizers Official Method.

STORAGE AND DISPOSAL:

PESTICIDE DISPOSAL:

Do not contaminate water, food or feed by storage or 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:

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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INSERT 1

For Potato Storage Area & Equipment Disinfecting: Preclean hard surfaces by removing heavy soil or gross filth. Disinfect with 1 ounce Ster-Bac to 2 gallons of water (400 ppm). For disinfecting previously cleaned porous surfaces, use 1 ounce Ster-Bac to 1 gallon of water (800 ppm). Flush surfaces thoroughly. Food contact surfaces which are disinfected, must be thoroughly rinsed with potable water prior to reuse.

KLENZADE
Division of Ecolab Inc.

STER-BAC (EPA REGISTRATION NO. 1677-43)
NEW USE AMENDMENT 1/8/88

MASTER LABEL MODIFICATION

SELF SANITIZING COATING

Use a high quality airless 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.

Surfaces must be free of dust, soil and grease. Clean prior to application if necessary.

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. Allow to dry.

Coverage of 4000-5000 square feet per gallon of STER-BAC is typical for hard, non-absorbent surfaces.

RESIDUAL SELF SANITIZING

After the coating has been formed, surfaces can be sanitized by wetting with a spray of cool water. The surface must remain moist for at least five minutes. Duration of residual self sanitizing is dependent upon surface exposure conditions. The Klenzade representative will make recommendations for reapplication.

REMOVAL

Coatings can be removed from surfaces with mildly acidic detergents such as Klenzade AC-3 (supplemented with Klenz-Foam) or Foam-Shine.

KLENZADE®

EPA Reg. No. 1677-43 EPA Est. No. 1677-IL-2

STER-BAC®

Quaternary Ammonium Sanitizer

ACTIVE INGREDIENTS:
(n-Alkyl [50% C_{14}, 40% C_{12}, 10% C_{16}] dimethyl benzyl ammonium chloride) 10.0%
INERT INGREDIENTS: 90.0%
TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panel for first aid instructions and additional precautions.

Manufactured by: KLENZADE, Division of Ecolab Inc., Ecolab Center St. Paul, MN 55102, ©, 1987

NET CONTENTS:

1 U.S. GAL. (3.78 l)

REGISTRANT: PESTICIDE DATA SHEET ECOLAB INC ECOLAB CENTER ST. PAUL MN 55102

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a 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 gallon of water (800 ppm). Flush surfaces thoroughly or apply by mopping or sponging onto the surface. All surfaces should be exposed to the sanitizing solution for a period of not less than 1 minute.

DISINFECTING

Disinfect previously cleaned hard surfaces such as walls, floors, woodwork, sinks, bathroom fixtures, with 1 oz. of Ster-Bac to 2 gallons 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 gallon of water (800 ppm). Flush surfaces thoroughly. All surfaces should be exposed to the sanitizing solution for a period of not less than 1 minute. Food contact surfaces which are disinfected, must be thoroughly rinsed with potable water prior to reuse.

Fogging can be used as an adjunct to acceptable manual cleaning and disinfecting as described above. Prior to fogging as an adjunct to acceptable manual cleaning and disinfecting, food products and packaging materials must be removed from the room or carefully protected. 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 gallon of water providing 1200 ppm active quaternary. Vacate the area of all personnel for a minimum of 2 hours after fogging. All food contact surfaces must then be thoroughly rinsed with potable water or a Ster-Bac solution of 200 ppm active quaternary. Allow surfaces to drain thoroughly before operations are resumed.

SANITIZING EQUIPMENT — FOOD PROCESSING PLANTS

For sanitation of equipment in food processing plants, clean and rinse equipment thoroughly. Then rinse equipment with 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 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 ½ oz. Ster-Bac to 2 gallons of water (200 ppm). Immerse all utensils for at least two minutes.
5. Drain and air dry.

GUARANTEED PHENOL COEFFICIENT AT 20°	
Staphylococcus aureus	75
Salmonella typhosa	50

NOTE: FOR MECHANICAL OPERATIONS prepared use solutions may not be re-used for sanitizing but may be re-used for other purposes such as cleaning.

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DANGER: Causes severe eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Avoid contamination of foods.

ENVIRONMENTAL HAZARDS:
This product is toxic to fish. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. 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.

FIRST AID

EXTERNAL: Immediately flush skin with plenty of water. Remove and wash contaminated clothing.
EYES: Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.
INTERNAL: If swallowed, immediately drink a large quantity of milk, egg whites or gelatin solution. If these are not available, drink large quantities of water.
GET MEDICAL ATTENTION IMMEDIATELY
FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE: 1-800-328-0026.

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. Recommendations of the U.S. Public Health Service in waters up to 550 ppm of hardness calculated as $CaCO_3$ when tested by the A.O.A.C. Germicidal and Detergent Sanitizers Official Method.

STORAGE AND DISPOSAL:

PESTICIDE DISPOSAL:
Do not contaminate water, food or feed by storage or 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:
Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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KLENZADE®
Division of Ecolab Inc

STER-BAC (EPA REGISTRATION NO. 1677-43)
NEW USE AMENDMENT 1/8/88

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

SELF-SANITIZING COATING:

Using appropriate equipment, **STER-BAC** can be applied together with Klenzade **KX-6033** as an adjuvant to yield a coating that is self-sanitizing. See Technical Bulletin.

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KLENZADE®
Division of Ecolab Inc.

TECHNICAL BULLETIN

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

The Problem:

Dairy, beverage and food processing plant operators want to improve the level of sanitation of environmental surfaces in their plants. 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 anti-microbial 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 need an antimicrobial product that would maintain 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. 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 I 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 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, 2.5×10^8 CFU). Log reductions in bacterial count due to exposure to these treatments are presented in Table I.

TABLE I

Surface Treatment	Exposure (minutes)	Log Reductions After Water Exposure 0	5	10	15	60
Ster-Bac Coating		>6.4	5.8	3.1	3.4	3.6
Ster-Bac Solution		>6.4	0.3	0.5	0.3	0.0

The laboratory results demonstrate the effective sanitizing residual of the **Ster-Bac** coating remains after exposure to 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 airless spray system equipped with a mixing spray gun. Satisfactory results have been obtained with a Binks Formulator Model K spray system using a Model 43 P spray gun with a fan spray tip (163-621) operating at 45 psi.

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

Surfaces must be free of dust, soil and grease. Clean 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.

Coverage of 4000-5000 square feet per gallon of **Ster-Bar** is typical for hard, non-absorbent surfaces.

Residual Self-Sanitizing:

After the coating has been formed, surfaces can be sanitized by wetting with a spray of cool water. The surface must remain moist for at least five minutes to obtain the sanitizing effect. For surfaces routinely exposed to incidental water contact, routine spray is not required. Avoid manual scrubbing or abrasion of the coated surfaces, since that would remove the coating.

Duration of residual self sanitizing is dependent upon surface exposure conditions. Routine reapplication over an existing coating is possible. The Klenzade representative will make recommendations for reapplication.

Removal:

Coatings can be removed from surfaces with mildly acidic detergents such as Klenzade AC-3 (supplemented with Klenz-Foam) or Foam-Shine.

EPA Registration No. 1677-43.

12/89

ADBAC / HYAMINE 3500 / PC 069105

Page _____ is not included in this copy.

Pages 11 through 24 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.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

X FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ 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.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Petition or File Symbol 1677-43

Date Division Received 01-12-88

Data Accession No. 404704-01 & 404704-02

Product Manager 31 (Lee)

Product Name Ster-Bac® Quaternary Ammonium Sanitizer

Company Name Klenzade, Division of Ecolab Inc.

202.0 Recommendations

202.1 Efficacy Supported By The Data

The submitted data developed by the A.O.A.C. Germicidal Spray Products as Disinfectants Test Method are adequate to support efficacy of the Ster-Bac-Adjuvant KX6033 mixture (1:1) as a hospital disinfectant when each component is simultaneously dispensed through a special spraying device to apply and thoroughly wet precleaned hard, non-porous surfaces with the solution mixture for a 10 minute contact time.

202.2 Inadequate Data

The submitted data developed by the Sanitizer Test (for non-food contact surfaces) to demonstrate residual self-sanitizing activity (≥ 99.9% reduction) of the 1:1 Ster-Bac-Adjuvant KX6033 coated hard surface after exposure to 60 minutes of distilled water shower spray against Staphylococcus aureus and Enterobacter aerogenes at 21°C for a 5 minutes contact are inadequate. See 202.3 below.

202.3 Evaluation of Protocol

The basic methodology of the testing procedure is considered suitable for the evaluation of self-sanitizing activity of residual chemical on hard surfaces that are likely to become wetted. However, the following qualifications or modifications must be taken in to consideration:

If it is intended or claimed that the treated surface will retain the residual activity after multiple challenges or more extended usage, test and control surfaces must be recontaminated with the test inoculum at multiple intervals for as long as it is claimed that the surface will provide residual activity. Sufficient replication (numbers of surfaces) will be necessary so as to maintain the integrity of the surfaces over the entire test period, for example the last items or surfaces to be assayed in the study must be subjected to all of the repeated challenges during the test period, but only to the last assay procedure during that period. With multiple challenges, an organic soil load (5% blood serum) should be added in the inoculum.

Wear test employed in the protocol must be conducted under the worst conditions which are likely to be encountered under normal conditions of use, such as abrasion, temperature, organic soil load, leaching by moisture, etc. Wear test employed in the protocol, exposure of treated tiles to 60 minutes of water spray is inadequate to simulate worse-case in-use effects of wearing the surface to the end-point of its use-life.

For residual self-sanitizing claims, the guidelines state that it must be demonstrated that at least 99.9% (3-log) reduction in the numbers of infectious test microorganisms occurs on the treated surface. This reduction must be shown over the numbers on the parallel untreated control surface or the "zero-time" control surface, whichever is less. Therefore, a "zero-time" bacterial numbers recovery determinatons should be performed to show the numbers of viable bacteria on the control surface.

Inoculum of the test microorganisms at a sufficient concentration to provide at least 10^4 survivors on the parallel control surface must be employed for initial and subsequent chalenges.

In use situations where the chemical residue is intended to be reactivated under low moisture conditions (e.g. moisture provided by direct body contact with the treated surface), an inoculum volume of 0.01 to 0.03 ml per surface (e.g., one inch square) would be considered representative of such conditions.

Calibrated bacteriological loop should be used to inoculate and spread inoculum over the test surface . Use of glass hockey stick to spread inoculum over the test surface are not acceptable.

Inoculated tiles should be dried at 37°C in vertical position in sterile petri dish $\geq$ 20 minutes but $\leq$ 60 minutes. Five minutes air dry at room temperature (22°C $\pm$ 1°C) is inadequate.

After a suitable exposure time quantitative recovery of test bacteria from test surface should be by washing the surface with adequate agitation in appropriate media or diluting fluid containing appropriate neutralizers. A sterile cotton swatch wiped over a test surface to recover test bacteria is not acceptable. Smaller size samples (e.g. 1 x 1 in-square surface) with and without antimicrobial agent may be necessary to perform this step.

The proposed protocol is for pre-cleaned surfaces. In use situations where the chemical residue is intended to be effective as a self-sanitizer in the presence of organic soil load, 5% blood serum should be added to the inoculum.

It is recommended that a neutralizer appropriate for the particular chemical being tested should be employed in the recovery solution. A preliminary test should be conducted with the specific chemical to confirm the absence of carry-over bactericidal effects of the antimicrobial in the diluting and culturing procedures (subculture media).

The exposure period, relative humidity and temperature, employed in the protocol must be the same as those which are likely to be encountered under normal conditions of use.

203.0 Labeling

a. In lieu of data delete residual self-sanitizing claims.

b. Include the major areas in which the product is recommended for use (e.g. homes, schools, restaurants, dairies, food processing plants).

c. Under the heading "STER-BAC® Quaternary Ammonium Sanitizer" include "SANITIZER ◦ DISINFECTANT ◦ DEODORIZER".

d. Under DISINFECTING" include methods of application and contact time necessary for effectiveness. Refer to items 5 and 6 of DIS/TSS-15 enclosure.

e. Under "Fogging"

1. Revise the statement "Fog desired areas using one quart per 1000 cu.ft....." to read "After cleaning fog desired areas using one quart per 1000 cu.ft....."

2. Include contact time necessary for effectiveness.

3. Revise the statement "All food contact surfaces must then be thoroughly rinsed with potable water or Ster-Bac solution of 200 ppm active quaternary. Allow surfaces to drain thoroughly before operations are resumed" to read "All food contact surfaces must then be thoroughly rinsed with Ster-Bac solution of 200 ppm active quaternary (1/2 oz/2 gal) prior to use. Allow surfaces to drain thoroughly and air dry before opertions are resumed"

f. Delete Phenol Coefficient claims.

g. Under "For Potato Storage Area & Equipment Disinfecting" include methods of application and contact time necessary for effectiveness. Refer to items 5 and 6 of DIS/TSS-15 enclosure.

204.0 Technical Bulletin

Comments listed under labeling also applies to Technical Bulletin.

AOAC / HYAMINE 3500 / PC 069105

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Pages _____ through _____ are not included in this copy.

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U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

ECOLAB
370 WABASHA ST.
ST PAUL, MN 55102

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 01/12/88. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

Your submittal was found to be substantially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exception(s) noted below. A copy of your bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents, and correct the noted exception(s) in future data submittals. If deficiencies were found which apply to your overall submission, they are described following this paragraph. If the deficiencies apply to specific studies, they are listed below following the applicable identification number or MRID. Thank you for your cooperation.

Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions.

If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Please include a copy of your transmittal for each copy of your submittal.

ECOLAB

Ecolab Inc.

Ecolab Center
St. Paul, Minnesota 55102

January 5, 1988

Mr. John H. Lee
Product Manager (31)
Registration Division Programs (TS-767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Lee:

Subject: STER-BAC, EPA Reg. No. 1677-43
Application for Amendment to Register a New Use

This application for amendment of STER-BAC is to add a new use pattern wherein the product is applied separately, but in combination with a specific acrylate copolymer to yield a self-sanitizing residue on hard surfaces. (See confidential attachment entitled CHEMICAL EXPLANATION OF THE STER-BAC BASED SELF-SANITIZING COATING.)

This coating combination would be marketed for use on non-food contact surfaces in food, dairy and beverage processing operations. The test methodology to document the residual self sanitizing claim was developed specifically to simulate realistically the use conditions for the coating formed in this type of application. Mr. Dale Fredell, Ecolab Inc., met with EPA Staff on two occasions to discuss test methodology. On October 30, 1985 he met with Mr. Dennis Guse for preliminary discussions on the test protocol. On July 8, 1987, Mr. Fredell met with Mr. John Lee and Mr. William Campbell. The "Method for the Microbiological Evaluation of Residual Self-Sanitizing Coatings" was discussed in detail. A means to demonstrate efficacy after exposure to copious amounts of water, such as the "shower apparatus" described in the method, was considered to be a reasonable approach. Mr. Campbell indicated that the methodology should be satisfactory for this testing.

With reference to the active ingredient (dimethyl benzyl ammonium chloride) in the product, please be aware that Ecolab is fulfilling EPA's requirements for re-registration of the ADBAC Quats by participating in the CSMA Joint Venture for cooperative data development.

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Enclosed are the following:

Vol. I - Transmittal Document

1. Product manager information: Confidential chemical explanation referred above.
2. Application for pesticide amendment, EPA form 8570-1.
3. Confidential Statement of Formula, EPA form 8570-4.
4. Certification with respect to citation of data.
5. Master label, for EPA filing, which has been amended to include directions for use for the new application (5 copies).
6. A short form amendment for a label statement to direct reference to the Technical Bulletin which details instructions for application of STER-BAC to yield a self sanitizing residue (5 copies).
7. Draft of the above referenced Technical Bulletin (5 copies).
8. List of Submitted Efficacy Studies as follows: (3 copies)

Vol. II - Study Title: STER-BAC Residual Self-Sanitizing Activity with Test Method Attachment (10/26/87) (Guideline 91-2) (Project ID 7196A) → 40470401

Vol. III - Study Title: STER-BAC-SPRAY DISINFECTANT (with Coating Adjuvant) (11/25/87) → 40470402 (Guideline 91-2) (Project ID 7196B)

Respectfully submitted,

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AMO:jhb