UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

June 24, 2002

MEMORANDUM:

Subject: Efficacy Review EPA Reg. No. 1677-43 Ster-Bac
DP Barcode 281365
Case No. 037306

From: Nancy Whyte, Microbiologist NKW
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

To: Velma Noble/Jacquie McFarland
Regulatory Management Branch I
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Thru: Emily Mitchell, M.S., Team Leader Emily Mitchell 7/19/02
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Lonza , Inc.
17-17 Route 209
Fairlawn, NJ 07410

Formulation Label:

Active Ingredient(s)	**% by wt.**
n-Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride	10.00%
Inert ingredients	90.00%
Total ingredients	100.00%

I. Background:

The registrant has submitted an application to add a label claim as a food-contact sanitizer against *Listeria monocytogenes*. This product is used as a disinfectant and deodorizer

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as well as a food-contact sanitizer for commercial and institutional use only. The efficacy testing report was submitted in one document MRID 456048-01. Also added to the label are claims for algae and slime control in cooling and processing waters, but no efficacy data are required since public health claims are not being made.

II. Use Directions:

The directions on the label for general disinfection for non-food contact surfaces specify a dilution of 1 ounce of product in 1-2 gallons water (400-800 ppm) which is applied with a coarse spray or foam on surface or by dipping for an exposure of 10 minutes. The label claim for effectiveness of the product against *Listeria monocytogenes* is made in the directions for sanitizing equipment in food processing plants and restaurants. Gross food particles and excess soil should be removed by pre-flushing or scraping, washed with a "good detergent or compatible cleaner", rinsed thoroughly with clear water and followed by a rinse with the sanitizing solution of 1 ounce of product in 4 gallons of water (200 ppm). All surfaces should remain wet for an exposure of not less than 1 minute. The equipment should be allowed to drain thoroughly and air dry following the exposure period. The same directions are given for sanitization of eating and drinking utensils. There are additional directions for sanitization of equipment using an elevated temperature of 120 deg. F, a dilution of 1 ounce of product in 10 gallons of water, and a 1 minute exposure time.

III. Agency Standards for Proposed Change:

The Agency standards for food-contact sanitization claims are found in DIS-TSS-4. Sanitizers applied to food contact surfaces are considered food additives and must have a food additive tolerance. Recommendation of a potable water rinse after treatment does not preclude this recommendation. The standard is based on the AOAC Available Chlorine Germicidal Equivalent Concentration Method for rinses formulated with iodophors, mixed halides and chlorine bearing chemicals for halide chemical products. For other chemical products such as quaternary ammonium compounds, chlorinated trisdoium phosphate, and anionic detergent-acid formulations must be substantiated with data derived from the AOAC Germicidal and Detergents Sanitizer Method. Confirmatory data are required for one test from one sample against the organism for which label claims are made.. When claims for effectiveness of the product in hard water are made, all required data must be developed at the level of hard water claimed. The performance standard required is that the product must demonstrate a 99.999% reduction in the number of microbes within 30 seconds. The results must be reported according to the actual count and percentage reduction over the control.

IV. Summary of Submitted Study:

The efficacy testing to support the proposed label claim was conducted at the Ecolab Inc. Research and Development Center in Mendota Heights, MN in May 2001 using Good Laboratory Practices as required. Two batches of an alternate formulation of the product (*Ster Bac Blu)* were used in the testing procedure. The test method followed Ecolab Microbiological Services SOP Method MS009-09 which was created from the Association of

Official Analytical Chemists (AOAC) *Germicidal and Detergent Sanitizing Action of Disinfectants* 960.09, Official Methods of Analysis of the AOAC International, 16th ed. 1995, fulfilling the Agency recommended test method requirements.

The test organism, *Listeria monocytogenes* ATTC 49594 was transferred daily on Brain-Heart Infusion Agar (BHIA) slants for at least 3 times but less than 30. The initial step in the preparation of the test substance was made by washing the agar surface with Phosphate Buffered Dilution Water (PBDW), and transferring the removed growth to PBDW. Individual French slants were inoculated by adding 2 ml of the PBDW mixture over the entire surface of the slant and pouring off the excess prior to overnight incubation at 37 +/- 2 °C. The final inoculum was prepared by harvesting the growth from the French slants by adding 3 ml of PBDW and sterile glass beads to each bottle, and washing the growth into a sterile vessel. The test suspension was then filtered thru wet sterile filter paper. Additional PBDW was added to yield a test inoculum which had a final % transmittance at 580 nm. This was determined to give final inoculum numbers for testing of 2.0×10^8 CFU/ml (200 ppm). This count was slightly higher than the projected count, but was determined not to affect the final results, since the product then passed a more stringent test resulting from the higher inoculum level.

Two batches of the product were provided by the registrant for testing, and both of these, D092101 and D120801, were used. The protocol for the testing stated that the concentration of the product that would be used would be at the lower certified limit (9.5%). The proposed dilution would therefore be 1.75 g in 998.25 g hard water(500 ppm) and 1.82g in 998.18g hard water (500 ppm) for the two batches, respectively. This dilution would yield a final concentration of 184.2 ppm for D092101 and 184.3 ppm for D120801. An error was made in the dilution, using higher amounts of both the product and hard water. A concentrate chemical concentration analysis test using potentiometric titration was performed on both batches of product. Results showed that Batch D092101 had a cationic concentration of 10.6 % and Batch D210801 had a cationic concentration of 10.2%. The limits fall between those stated on the Confidential Statement of Formula at 10.5-9.5% (+/- 3.4%) and did not adversely affect the test results.

For the actual testing, 99 ml of the test organism substance was dispensed into duplicate 250 ml Erlenmeyer flasks and placed in a 25 +/- 2° C water bath. After the temperature reached equilibrium, the flasks were whirled and 1 ml. of the product was added, avoiding touching the sides of the flask with the delivery pipet. Following the 30 sec. exposure period, 1 ml of the organism/product mixture was transferred to a 9 ml. neutralizer blank (Chambers Medium) and mixed. Pour plates using one ml. and 0.1 ml from the neutralizer tubes were prepared in quadruplicate and incubated for 48 +/- 4 hr. at 37 +/- 2° C.

Neutralization controls were run on each test batch using 1 ml of the test substance and 0.1 of the organism suspension in 9 ml of neutralizer, 1 ml. of hard water and 0.1 ml of the organism suspension in 9 ml of neutralizer, and 0.1 ml of the product and 10 ml of the PBDW. These controls were enumerated by plating 1.0 ml and 0.1 ml on BHIA. Sterility controls were run in the same manner on the diluent, the neutralizer medium, PBDW, and BHIA. All controls were within specifications except the aforementioned Inoculum Enumeration.

V. Labeling:

1. The additional claim on Page 5 relating to use in federally inspected meat and poultry plants that the product may be "added to water to cook and cool containers of meat and poultry products..." is not allowed and must be removed from the label.

VI. Comments and Recommendations:

1. This product when diluted with 500 ppm synthetic hard water to 196 ppm demonstrated effectiveness against *Listeria monocytogenes*, ATCC 49594 after a 30 second exposure time at 25 +/- 2°, reducing the bacterial count by 99.999%, meeting the efficacy requirements for a food-contact sanitizer.

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PM: Please note:

The registrant is making a label claim for this product as a residual self-sanitizer. This claim was not on the label accepted in 1999 and included in this data package as the last accepted label. Please do a label review to determine if such a claim is allowed.

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STER-BAC

QUATERNARY AMMONIUM SANITIZER - DISINFECTANT - DEODORIZER

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

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.

DISINFECTING
Disinfect previously cleaned hard nonporous surfaces such as walls, floors, woodwork, sinks, bathroom fixtures, with 1 oz **Ster-Bac** to 2 gal. 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 gal. of water (800 ppm). Flush surfaces thoroughly or apply by mopping, sponging or coarse spraying on surface. All surfaces should be exposed to the disinfecting solution for a period of not less than 10 minutes. Food contact surfaces that 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 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.

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.

GENERAL DISINFECTANT – NON-FOOD CONTACT SURFACES
Pre-clean surfaces. Disinfect non-food contact surfaces such as 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). Apply by dipping, coarse spray or foam on surface. All surfaces should be exposed to the disinfecting solution for a period of not less than 10 minutes.

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 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.

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.

For use in federally inspected meat and poultry plants. May be added to water to cook and cool containers of meat and poultry products to prevent staining of containers and to control corrosion and deposit formation on surfaces of 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

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

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)
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

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