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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

February 4, 2005

MEMORANDUM:

Efficacy Review of EPA Reg. No. 1677-43 *Ster-Bac*
DP 310342

From: Nancy Whyte, Efficacy Team Leader (Acting)
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Feb 4, 2005

To: Velma Noble/Zenobia Jones
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Thru: Michele E. Wingfield, Chief
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Applicant: ECOLAB, Inc.
370 N. Wabasha St.
St. Paul, MN 55102

Formulation Label:	<u>% by wt.</u>
<u>Active Ingredient(s)</u>	
n-Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride.....	10.0%
Other ingredients.....	<u>90.0%</u>
Total	100.0%

I. Background:

The product, STER-BAC (EPA Reg. No. 1677-43), is an EPA-approved sanitizing rinse for use on hard, non-porous food contact surfaces in institutional and commercial environments. The label claims that the product is effective as a sanitizing rinse at 200 ppm active quat in the presence of 500 ppm hard water. The applicant requested an amendment to the registration of this product to add a claim for effectiveness against *Enterobacter sakasakii*.

Studies were conducted at Ecolab Inc.'s Research and Development Center, located at 840 Sibley Memorial Highway in Mendota Heights, MN 55118.

This data package contained EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-35 (Data Matrix), a letter from the applicant to EPA (dated October 5, 2004), one study (MRID No. 463803-01), a Statement of No Data Confidentiality Claims for the study, the proposed label, and the last accepted label (dated August 31, 2004).

II. Use Directions:

The product is designed to be used as a sanitizing rinse on previously cleaned, hard, non-porous food contact surfaces such as meat and poultry or fruit and vegetable conveyers, eating and drinking utensils, and equipment in restaurants and food processing plants. Directions on the proposed label provided the following information regarding preparation and use of the product as a sanitizing rinse: Remove gross food and soil by a pre-flush or pre-scrape. Wash with a good detergent or compatible cleaner. Rinse with clear water. Prepare a use solution by adding 1 ounce of the product to 4 gallons of water (a 1:512 dilution; 200 ppm active quat). Expose surfaces to the use solution for at least one minute. Allow surfaces to drain and air dry.

III. Agency Standards for Proposed Claims:

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces; Additional Bacteria)

There are cases where an applicant requests to make claims of effectiveness against additional bacteria for a product that is already registered as a sanitizing rinse for previously cleaned, food contact surfaces. In the case of this product which is already registered as a food-contact sanitizer, only confirmatory efficacy data is required. For sanitizing rinses for previously cleaned, food contact surfaces, 2 product samples, representing 2 different product lots, must be tested against each additional microorganism for which a label claim for effectiveness of the product is requested. Results must show a bacterial reduction of at least 99.999% in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control.

Furthermore, according to information in the above AOAC test method itself, counts on number controls for the product should fall between 75 and 125 x 10⁶/mL for percent reductions to be considered valid. Label directions for use, however, must state that a contact time of at least 1 minute is required for sanitization. These Agency standards are presented in DIS/TSS-4 and -17, as well as the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method.

Supplemental Claims

On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. These Agency standards are presented in DIS/TSS-2.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDY

1. MRID 463803-01 "STER-BAC Food Contact Surface Sanitizing Efficacy at 25°C," by Matthew J. Finley. Study conducted at Ecolab Inc., Research and Development Center. Study completion date – June 14, 2004. Study Identification Number 0400004.

This study was conducted against *Enterobacter sakasaki* (ATCC 12868). Two lots (Lot Nos. DJR121A and DJR121B) of the product, STER-BAC, were tested using the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. A 184.3 ppm use solution was prepared by adding 0.87 g of the product to 500 ppm synthetic hard water (titrated at 505 ppm) to bring the total weight to 500 g (a 1:512 dilution). A 99-mL aliquot of the use solution was transferred to a 250-mL Erlenmeyer flask and placed in a water bath at 25±2°C and allowed to equilibrate. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Lethen broth exactly 30 seconds after the addition of the bacterial suspension. The neutralizer tubes were mixed. Aliquots of 1.0 mL and 0.1 mL taken from the neutralizer tubes were pour plated in quadruplicate using tryptone glucose extract agar. All plates were incubated for 48±4 hours at 32±2°C and the colonies were counted. Controls included those for neutralization, sterility, purity, enumeration of the test system, and confirmation of the challenge microorganism.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: The applicant provided the data for a failed trial set up on February 25, 2004. In that trial, the concentration of the use solution tested was not properly calculated. Thus, the test was invalid. These data were not used to evaluate efficacy of the test product. See "Invalid Data Appendix" of the laboratory study.

V RESULTS

MRID Number	Organism	Lot No.	Time	Average No. Surviving	Microbes Initially Present	Percent Reduction
				(CFU/mL)		
463803-01	<i>Enterobacter sakasaki</i>	DJR121A	30 sec.	<10	2.40 x 10 ⁸	>99.999
		DJR121B	30 sec.	10	2.40 x 10 ⁸	>99.999

VI CONCLUSIONS

1. The submitted efficacy data (MRID No. 463803-01) support the use of a 1:512 dilution of the product, STER-BAC, as a sanitizing rinse against *Enterobacter sakasaki* on previously cleaned, hard, non-porous food contact surfaces in the presence of 500 ppm hard water for a contact time of 30 seconds. A 99.999% reduction in population was observed. Number controls exceeded 125 x 10⁶/mL. Despite this, test results are considered to be valid because the average number of survivors was 10 CFU/mL or less. Neutralization control testing indicated that the neutralizer was effective and not detrimental to the challenge microorganism. Purity controls were reported as pure. Sterility controls did not show growth.

VII RECOMMENDATIONS

1. The proposed label claims that a 1:512 dilution of the product, STER-BAC, is an effective sanitizing rinse for use on previously cleaned, hard, non-porous, food contact surfaces against *Enterobacter sakasaki* for a contact time of 1 minute in the presence of 500 ppm hard water. Efficacy data provided by the applicant support this claim.
2. The proposed label now specifically claims that the product, STER-BAC, is an effective sanitizing rinse for use on food contact surfaces against *Listeria monocytogenes*, *Escherichia coli*, and *Staphylococcus aureus*. Previous labels did not list any of these organisms. Efficacy data were not submitted in the data package to support use of the product as a sanitizing rinse on food contact surfaces against *Escherichia coli* and *Staphylococcus aureus*. The Data Matrix provided in the data package does not list any efficacy studies supporting sanitizing of food contact surfaces against these organisms (except at elevated temperatures).

Note: This product was registered in 1975 when there was no requirement to list specific organisms on the label. Limited efficacy data for the testing of organisms required to support a food contact claim (*E. coli* and *Staph. aureus*) is on file with the registrant. At this time that thirty year-old data is acceptable to the Agency. In the near future when this product is subject to re-registration, new efficacy data conducted using current Agency standards will be required for this product to support all claims for effectiveness now appearing on the label.

3. The instructions for using the product in fogging disinfectant applications do not include precautions for early-reentry into the treated area. Such instructions often specify use of a NOSH-approved respirator during early-reentry.
4. The applicant must make the following revisions to the proposed label, as appropriate:
 - Under the "Directions for Use" section [see page 2 of the proposed label], change "in manner inconsistent" to read "in a manner inconsistent."
 - Under the "General Disinfection" section and the "General Disinfection of Meat, Poultry, and Other Food Processing Facilities" section [see page 2 of the proposed label], change "course spray" to read "coarse spray."
 - Under the "Sanitizing - Non-Porous Gloved Hands" section [see page 3 of the proposed label], change "storage areas food plants" to read "storage areas of food plants" and change "1 ounce of this project" to read "1 ounce of this product."