



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

September 27, 2011

MEMORANDUM

Subject: Revised Efficacy Review for EPA Reg. No. 1677-EGA, RAC 100BL;

From: Tajah L. Blackburn, Ph.D., Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

To: Velma Noble PM 31/Drusilla Copeland
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: EcoLab, Inc.
370 Wabasha Street North
St. Paul, MN 55102

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
n-Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₈) dimethyl benzyl ammonium chloride.....	0.0600%
Di-n-Octyl dimethyl ammonium chloride.....	0.0225%
Di-n-Decyl dimethyl ammonium chloride.....	0.0225%
n-Octyl Decyl dimethyl ammonium chloride.....	0.0450%
<u>Other Ingredients</u>	<u>99.8500%</u>
Total.....	100.0000%

I BACKGROUND

The product, RAC 100BL (EPA File Symbol 1677-EGA), is a new product. The applicant requested to register the product for use as sanitizer and fungistat/ mildewstat on hard, non-porous, non-food contact surfaces in food processing environments. The product also has residual sanitizing activity. In response to the Agency's review (dated August 3, 2011), the registrant has provided a rationale to explain residual self-sanitizing application modifications.

II USE DIRECTIONS

The product is designed for sanitizing hard, non-porous, non-food contact surfaces. The product may be used to treat hard, non-porous surfaces, including: ceilings, drip pans, exterior HVAC surfaces, food processing equipment (which is not in service), piping, racks, trailers, troughs, and walls. The proposed label does not identify the types of surfaces on which the product may be used (e.g., stainless steel, glass). Directions on the proposed label provide the following information regarding use of the product as a sanitizer: Remove gross soils and particles from surfaces. Wash with a recommended detergent solution and rinse thoroughly with potable water. Apply product using spray equipment, brush, roller, or pad, so that all surfaces are visibly coated. Surfaces should be exposed to the sanitizing coating for a period of not less than 5 minutes.

The product also provides residual sanitizing activity for up to 30 days on hard, non-porous, non-food contact surfaces, including: ceilings, drip pans, exterior HVAC surfaces, food processing equipment (which is not in service), piping, racks, trailers, troughs, and walls. Directions on the proposed label provide the following information regarding use of the product for this purpose: Remove gross soils and particles from surfaces. Wash with a recommended detergent solution and rinse thoroughly with potable water. For best results, allow surface to dry thoroughly before applying product. Apply product using spray equipment, brush, roller, or pad, so that all surfaces are visibly coated. Ensure sufficient coverage.

The product is designed for controlling mold on hard, non-porous surfaces and porous surfaces. Directions on the proposed label provide the following information regarding use of the product as a fungistat/ mildewstat: Remove gross soils and particles from surfaces. Wash with a recommended detergent solution and rinse thoroughly with potable water. For best results, allow surface to dry thoroughly before applying product. Apply product using spray equipment, brush, roller, or pad, so that all surfaces are visibly coated. Porous surfaces may require multiple coats to achieve the coverage recommended on the proposed label.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil

load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

There are cases where an applicant requests to make claims of effectiveness against additional microorganisms for a product that is to be used as a sanitizer for non-food contact surfaces. The DIS/TSS standards are silent on this matter. Confirmatory test standards would apply. Therefore, 2 product samples, representing 2 different product lots, should be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. Furthermore, according to information provided in Section 12.3.2 of ASTM E1153-94, which is a test method for the efficacy of sanitizers for non-food contact surfaces, "an average of at least 7.5×10^5 organisms must have survived on the inoculated control squares for the test to be valid."

Residual Self-Sanitizing Products

The effectiveness of sanitizers that bear claims of residual activity must be supported by data that show that the product continues to reduce the number of challenge microorganisms over an identified period of time. Products with residual self-sanitizing activity keyed to the presence of moisture on surfaces should be tested in a controlled or simulated in-use study. The study should be designed in consultation with the Agency. Products with residual self-sanitizing activity intended for use on dry surfaces should be tested in accordance with Protocol #01-1A, Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Non-Porous Surfaces. These Agency standards are presented in OPPTS 810.2100.

Mildewstats/Fungistats on Hard Surfaces

The effectiveness of mildewstats and fungistats may be supported by efficacy data derived using the EPA Hard Surface Mildew Fungistatic Test Method. All ten treated tiles must be free of fungal growth after 7 days. To be considered a valid test, untreated control tiles must be at least 50% covered with fungal growth after 7 days. Agency standards are presented in the Pesticide Assessment Guidelines, Subdivision G, Section 93-30, Product Performance, November 1982.

Mildewstats/Fungistats on Indoor Articles or Surfaces Composed of Wood

The effectiveness of mildewstats and fungistats may be supported by efficacy data derived using the EPA Wood Block Mildew Fungistatic Test Method. Tests may be performed against *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (NRRL-3765 or ATCC 32333). All ten treated blocks must be free of fungal growth after 7 days. To be considered a valid test, untreated control tiles must be at least 50% covered with fungal growth after 7 days. Agency standards are presented in the Pesticide Assessment Guidelines, Subdivision G, Section 93-30, Product Performance, November 1982.

VI REGISTRANT'S RATIONALE FOR SELF-SANITIZING USE SITES

Overview: The Ecolab protocol Residual Sanitizing Activity on Hard Non-Porous Surfaces is based on the "Clorox Protocol" (Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces). Both protocols are intended to evaluate residual sanitizing activity on hard, nonporous surfaces. The Clorox Protocol was designed for frequently contacted or touched surfaces in a residential environment designed for frequently contacted or touched surfaces in residential environment, while the Ecolab residual sanitizing protocol was designed for commercial environmental surfaces which are not contacted/touched at all or very infrequently as compared to the Clorox use pattern.

Clorox Protocol: The Clorox protocol calls for a number of dry and/or moist wear or abrasion cycles with intermittent re-inoculations on the coated surfaces over a 24-hours period of time. For example, the Clorox protocol may include up to 12 wear cycles and five (5) re-inoculations over a 24 hour evaluation period.

Clorox Protocol Procedure

"Wear" and Reinoculation Procedure

1. Initial inoculation with test organism
2. Apply test product
3. Wear cycle with dry cloth (wear #1)
4. Reinoculation with test organism
5. Wear cycle with moist cloth (wear #2)
6. Reinoculation with test organism
7. Wear cycle with dry cloth (wear #3)
8. Reinoculation with test organism
- End of first-----
9. Wear cycle with moist cloth (wear #4)
10. Reinoculation with test organism
11. Wear cycle with dry cloth (wear #5)
12. Reinoculation with test organism
13. Wear cycle with moist cloth (wear #6)
14. Repeat until 12 wear cycles are completed
15. Sanitizer test performed at least 24 hours after application of the test product.

Ecolab Residual Sanitizer Protocol: The Ecolab Residual Sanitizer Protocol was adopted from the Clorox protocol and has been approved by the Agency. A draft product label identifying commercial use areas in food processing facilities was included in the discussion and accompanied the approved protocol. Both the Clorox and Ecolab residual sanitizer protocols include re-inoculation cycles during the test duration. The Ecolab residual protocol spans a 30-day test period where the test articles are inoculated a total of ten (10) times (on days 1, 2, 8, 9, 15, 16, 22, 23, 29, and 30). This represents back-to-back inoculations at the beginning and the end of the test period as well as at approximately the $\frac{1}{4}$, $\frac{1}{2}$, and $\frac{3}{4}$ time points at approximately 1-week intervals. The re-inoculations are intended to simulate non-visible contamination of RAC 100 BL

coating during the 30-day coating life. The Ecolab Residual Sanitizer protocol is intended for surfaces which are not contacted or touched frequently, thus no wear or abrasion cycles are included in the test protocol. If the coating were to be visibly contaminated by touch or other means, label instructions direct the user to remove the coating and re-apply.

V CONCLUSIONS/LABEL RECOMMENDATIONS

1. The proposed label claims that the product, RAC 100BL, provides residual sanitizing activity for up to 30 days on pre-cleaned; hard, non-porous, non-food contact surfaces:

Staphylococcus aureus
Klebsiella pneumoniae
Escherichia coli O157:H7
Salmonella typhimurium
Listeria monocytogenes

These claims are acceptable as they are supported by the submitted data. These claims must be limited to include surfaces that are not touched, since the wear components of the test system were not included. The use sites can be expanded to dairy, meat, poultry, brewery, beverage and other food processing facilities, based on the rationale provided and use direction/use site restrictions and limitations.

2. The submitted efficacy data (MRID 484276-12) support the use of the product, RAC 100BL, as a fungistat/ mildewstat against *Aspergillus niger* and *Penicillium variable* on pre-cleaned, porous surfaces. No growth was observed 21 days after treatment. Testing was conducted on 3 product lots. Untreated control tiles exhibited growth of *Aspergillus niger* and *Penicillium variable* on at least 50% of each untreated tile surface; after several attempts for *Aspergillus niger*. Purity controls were reported as pure. The information provided by the registrant adequately addresses the observed issues with the carrier count. The proposed label claims supports the use of the product, RAC 100BL, to inhibit the growth of mold up to 14 days on pre-cleaned, porous surfaces. The information provided by the registrant is sufficient.

3. The following revisions to the proposed label are required:

- On page 1 of the proposed label, "expand to state on "untouched surfaces".