UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

August 3, 2011

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 1677-EGA, RAC 100BL;
DP Barcode: 388661

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

To: Velma Noble PM 31/Drusilla Copeland
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Applicant: EcoLab, Inc.
370 Wabasha Street North
St. Paul, MN 55102

Formulation from the Label:

Active Ingredient(s)	% by wt.
n-Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) 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%
Other Ingredients	99.8500%
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 addition, the product is being registered for use as a fungistat/ mildewstat on porous surfaces. Studies were conducted at ECOLAB located at the Ecolab Schuman Campus on 655 Lone Oak Drive, in Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated March 17, 2011), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-35 (Data Matrix), six studies (MRID 484276-09 through 484276-14), Statements of No Data Confidentiality Claims for all six studies, and the proposed label.

Note: The laboratory reports describe studies conducted for the product, KX-6207. The applicant's letter to EPA (dated March 17, 2011) states that the tested product, KX-6207, is an experimental number for the product, RAC 100BL, which is the subject of this efficacy report.

Note: EPA Form 8570-4 (Confidential Statement of Formula) contains Confidential Business Information. Data or information claimed by the applicant to be FIFRA confidential has not been included in this report.

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.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 484276-09 "KX-6207 Supplemental Non-Food Contact Surface Sanitizing Efficacy," Test Organisms: *Escherichia coli* O157:H7 (ATCC 43895), *Salmonella typhimurium* (ATCC 13311), and *Listeria monocytogenes* (ATCC 49594), by Laurinda Holen. Study conducted at ECOLAB. Study completion date – January 17, 2011. Study Number 1000061.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 43895), *Salmonella typhimurium* (ATCC 13311), and *Listeria monocytogenes* (ATCC 49594). Two lots (Lot Nos. RAC-290-12A and RAC-290-12B) of the product, KX-6207, were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153). The product was received ready-to-use. Testing was conducted on November 9, 2010 and November 15, 2010. Fetal bovine serum was added to each culture to achieve a 5% organic soil load. Five sterile stainless steel carriers (25 mm x 25 mm) per product lot per microorganism were inoculated with 0.03 mL of a 24±4 hour old suspension of test organism. According to the protocol, the inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers for *Escherichia coli* O157:H7 and *Salmonella typhimurium* were dried for 40 minutes at 30±2°C. The carriers for *Listeria monocytogenes* were dried for 30 minutes at 32±2°C. Drying was performed in a desiccator containing 86.5% glycerin for a portion of the drying time. Each carrier was transferred to a sterile medicine jar and treated with 5 mL of the product for 5 minutes at 15-30°C. Following exposure, 20 mL of 2X DE Broth was added to each medicine jar. According to the protocol, the jars were rotated on an even plane for ~50 rotations to suspend the surviving organisms. One (1.0) and 0.1 mL aliquots of the solutions were plated in duplicate on Brain Heart Infusion Agar. All subcultures were incubated for 48±4 hours at 35±2°C. Following incubation, the subcultures were visually enumerated. Controls included those for inoculum count, enumeration of control squares, purity, sterility, and neutralization confirmation.

Note: The laboratory reported a failed study set up on November 9, 2010. In the study, the inoculated control squares for *Salmonella typhimurium* and *Listeria monocytogenes* did not demonstrate an average of at least 7.5 x 10^5 surviving organisms. The

laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated on November 15, 2010 for *Salmonella typhimurium* and *Listeria monocytogenes*. See Appendix B of the laboratory report.

2. MRID 484276-10 "KX-6207 Residual Sanitizing Efficacy on Hard, Non-Porous, Non-Food Contact Surfaces," Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352), by Laurinda Holen. Study conducted at ECOLAB. Study completion date – January 24, 2011. Study Identification Number 1000058.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three lots (Lot Nos. RAC-290-12A, RAC-290-12B, and RAC-290-12C) of the product, KX-6207, were tested. The laboratory report referenced Protocol #01-1A, Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Non-Porous Surfaces. Each of the product lots tested were at least 60 days old at the time of testing. The product was received ready-to-use. Fetal bovine serum was added to each culture to achieve a 5% organic soil load. Sterile stainless steel carriers (1 inch x 1 inch) per product lot per microorganism were treated with 50 µL of the product. After treatment, the carriers were allowed to dry for at least 24±4 hours at 15-30°C. The carriers were then inoculated with 20 µL of a 24±4 hour old suspension of test organism. Inoculations were repeated on Days 2, 8, 9, 15, 16, 22, 23, 29, and 30. Five minutes after inoculation on Days 15, 22, and 30, five carriers per microorganism were transferred to sterile medicine jars and treated with 20 mL of DE Broth. The medicine jars were sonicated for 20±2 seconds, followed by agitation on an orbital shaker for 3 minutes at 250 rpm to suspend the surviving organisms. The neutralized solutions were serially diluted with phosphate buffered dilution water. The 10^0, 10^{-1}, and 10^{-2} dilutions were plated in duplicate on tryptone glucose extract agar. All subcultures were incubated for 48±4 hours at 35±2°C. Following incubation, the subcultures were visually enumerated. Controls included those for inoculum count, enumeration of control coupons, purity, sterility, and neutralization confirmation.

Note: The laboratory reported a failed study set up on October 13, 2010 (i.e., Day 15). In the study, the inoculated control coupons for *Staphylococcus aureus* did not demonstrate adequate growth. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated. See Appendix B of the laboratory report.

Note: Protocol deviations/amendments were observed in the study.

3. MRID 484276-11 "KX-6207 Hard Surface Mildew Fungistatic Efficacy," Test Organism: *Aspergillus niger* (ATCC 6275), by Laurinda Holen. Study conducted at ECOLAB. Study completion date – January 28, 2011. Study Number 1000053.

This study was conducted against *Aspergillus niger* (ATCC 6275). Three lots (Lot Nos. RAC-290-12A, RAC-290-12B, and RAC-290-12C) of the product, KX-6207, were tested using the EPA Hard Surface Mildew Fungistatic Test Method. The product was received ready-to-use. Each of the product lots tested was at least 60 days old at the time of testing. Testing was conducted on September 14, 2010, October 19, 2010,

and October 20, 2010. Testing was not conducted in the presence of an organic soil load. A culture of the challenge microorganism was prepared in accordance with the EPA method, with the few deviations. A 1 mL aliquot of a conidial suspension was added to 20 mL of sterile Czapek's Dox Broth. Sterile glazed ceramic tiles (25 mm x 25 mm) (10 per treatment) were used. The tiles were treated with 50 µL of the product and kept horizontal to dry. The tiles were dried for 24±4 hours at 15-30°C. Following the drying period, the surfaces of each test tile and each untreated control tile were sprayed with the *Aspergillus niger* conidia-Czapek suspension using a travel size spray bottle. The tiles were allowed to dry for 30±2 minutes at 35±2°C. Each tile (treated side up) was placed in an individual Petri dish containing water agar. The plates were incubated for 30 days at 26±2°C at ~95% relative humidity. The tiles were transferred to new water agar plates on Days 7, 14, and 21. On Days 7, 14, 21, and 30, the tiles were examined for the presence or absence of fungal growth. When no growth was visually observed, a magnified examination (~15X magnification) was performed. Controls included a positive growth control and a negative growth control and those for enumeration of test system and purity.

Note: Testing conducted on September 14, 2010 showed growth on one of the edges of one tile after 21 days and 30 days of incubation. Testing was repeated twice to verify efficacy of the product.

Note: Protocol deviations/amendments were reported.

4. MRID 484276-12 "KX-6207 Wood Block Mildew Fungistatic Efficacy," Test Organisms: *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333), by Laurinda Holen. Study conducted at ECOLAB. Study completion date – January 28, 2011. Study Number 1000054.

This study was conducted against *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333). Three lots (Lot Nos. RAC-290-12A, RAC-290-12B, and RAC-290-12C) of the product, KX-6207, were tested using the EPA Wood Block Mildew Fungistatic Test Method. The product was received ready-to-use. Each of the product lots tested was at least 60 days old at the time of testing. Testing was conducted on September 28, 2010, November 17, 2010, and December 1, 2010. Testing was not conducted in the presence of an organic soil load. Cultures of the challenge microorganisms were prepared in accordance with the EPA method. For testing conducted on September 28, 2010, the conidial suspension was diluted 1:10 in phosphate buffered dilution water. For testing conducted on November 17, 2010 and December 1, 2010, the conidial suspension was diluted 1:5 in phosphate buffered dilution water. A second dilution was made by adding 2 mL of Sabouraud Dextrose Broth (nutrient source), 16 mL of phosphate buffered dilution water, and 2 mL of the diluted conidial suspension. Pine sapwood wood blocks (25 mm x 25 mm x 15 mm) (10 per treatment) were used. The wood blocks were treated with four coats of the product. The product was allowed to dry between each coat. After the final coat, the surfaces of the wood blocks were dried for at least 24±4 hours at 15-30°C. Following the drying period, all sides of each test wood block and each untreated control wood block were lightly sprayed with the conidia-nutrient suspension using a travel size spray bottle. Each wood block was suspended in individual jars above 90 mL of water. The *Aspergillus niger* wood blocks were incubated for 21 days at 26±2°C. The *Penicillium variable* wood blocks were incubated for 30 days at 26±2°C. On Days 7, 14, and 21 (and Day 30 for *Penicillium variable*), the wood blocks were examined for the presence

or absence of fungal growth. When no growth was visually observed, a magnified examination was performed (~15X magnification). Controls included a positive growth control and a negative growth control and those for enumeration of the test systems and purity.

Note: Protocol deviations/amendments were reported.

Note: The laboratory reported a failed study set up on September 21, 2010. In the study, all positive growth controls for *Aspergillus niger* did not demonstrate 50% growth. In addition, on Day 14, growth was observed on 1 of the 10 wood blocks tested against *Aspergillus niger* using Lot No. RAC-290-12A. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated on October 19, 2010. See page 11 and Appendix B of the laboratory report.

Note: In the October 19, 2010 study, the positive growth controls for *Aspergillus niger* did not demonstrate 50% growth. Each of the 10 wood blocks had growth, but none of the wood blocks were covered with at least 50% growth. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated on October 20, 2010. See page 11 and Appendix B of the laboratory report.

Note: In the October 20, 2010 study, all positive growth controls for *Aspergillus niger* did not demonstrate 50% growth. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated on November 17, 2010. See page 11 and Appendix B of the laboratory report.

Note: In the November 17, 2010 study, the positive growth control for *Aspergillus niger* did not demonstrate 50% growth. Each of the 10 wood blocks had growth, but none of the wood blocks were covered with at least 50% growth. The laboratory did not accept the assay for this product lot. These data were not used to evaluate efficacy of the product. Testing was repeated on December 1, 2010. See page 11 and Appendix B of the laboratory report.

5. MRID 484276-13 "KX-6207 Supplemental Residual Sanitizing Efficacy on Hard, Non-Porous, Non-Food Contact Surfaces," Test Organisms: *Escherichia coli* O157:H7 (ATCC 43895), *Salmonella typhimurium* (ATCC 13311), and *Listeria monocytogenes* (ATCC 49594), by Laurinda Holen. Study conducted at ECOLAB. Study completion date – January 24, 2011. Study Identification Number 1000059.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 43895), *Salmonella typhimurium* (ATCC 13311), and *Listeria monocytogenes* (ATCC 49594). Two lots (Lot Nos. RAC-290-12A and RAC-290-12B) of the product, KX-6207, were tested. The laboratory report referenced Protocol #01-1A, Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Non-Porous Surfaces (modified). The product was received ready-to-use. Fetal bovine serum was added to each culture to achieve a 5% organic soil load. Sterile stainless steel carriers (1 inch x 1 inch) per product lot per microorganism were treated with 50 µL of the product. After treatment, the carriers were allowed to dry for at least 24±4 hours at 15-30°C. The carriers were then inoculated with 20 µL of a 24±4 hour old suspension of test organism (which differs from the 18-24 hour old suspension specified in DIS/TSS-10).

Inoculations were repeated on Days 2, 8, 9, 15, 16, 22, 23, 29, and 30. Five minutes after inoculation on Days 15, 22, and 30, five carriers per microorganism were transferred to sterile medicine jars and treated with 20 mL of DE Broth. The medicine jars were sonicated for 20±2 seconds, followed by agitation on an orbital shaker for 3 minutes at 250 rpm to suspend the surviving organisms. The neutralized solutions were serially diluted with phosphate buffered dilution water. The 10^0, 10^{-1}, and 10^{-2} dilutions were plated in duplicate on Brain Heart Infusion Agar. All subcultures were incubated for 48±4 hours at 35±2°C. Following incubation, the subcultures were visually enumerated. Controls included those for inoculum count, enumeration of control coupons, purity, sterility, and neutralization confirmation.

Note: Protocol deviations/amendments reported in the study were reviewed.

6. MRID 484276-14 "KX-6207 Non-Food Contact Surface Sanitizing Efficacy," Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352), by Laurinda Holen. Study conducted at ECOLAB. Study completion date – January 17, 2011. Study Number 1000060.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three lots (Lot Nos. RAC-290-12A, RAC-290-12B, and RAC-290-12C) of the product, KX-6207, were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153). Each of the product lots tested was at least 60 days old at the time of testing. The product was received ready-to-use. Testing was conducted on November 5, 2010 and November 15, 2010. Fetal bovine serum was added to each culture to achieve a 5% organic soil load. Five sterile stainless steel carriers (1 inch x 1 inch) per product lot per microorganism were inoculated with 0.03 mL of a 24±4 hour old suspension of test organism. According to the protocol, the inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers for *Staphylococcus aureus* were dried for 30 minutes at 32±2°C. The carriers for *Klebsiella pneumoniae* were dried for 31 minutes at 30±2°C. Drying was performed in a desiccator containing 86.5% glycerin for a portion of the drying time. Each carrier was transferred to a sterile medicine jar and treated with 5 mL of the product for 5 minutes at 15-30°C. Following exposure, 20 mL of 2X DE Broth was added to each medicine jar. According to the protocol, the jars were rotated on an even plane for ~50 rotations to suspend the surviving organisms. One (1.0) and 0.1 mL aliquots of the solutions were plated in duplicate on tryptone glucose extract agar. All subcultures were incubated for 48±4 hours at 35±2°C. Following incubation, the subcultures were visually enumerated. Controls included those for inoculum count, enumeration of control squares, purity, sterility, and neutralization confirmation.

Note: The laboratory reported a failed study set up on November 5, 2010. In the study, the inoculated control squares for *Klebsiella pneumoniae* did not demonstrate an average of at least 7.5×10^5 surviving organisms. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated on November 15, 2010 for *Klebsiella pneumoniae*. See Appendix B of the laboratory report.

Note: Protocol deviations/amendments reported in the study were reviewed.

V RESULTS

MRID Number	Organism	Lot No.	Total No. Surviving (CFU/carrier)	Parallel Control (CFU/carrier)	Percent Reduction
5-Minute Exposure Time					
484276-09	*Escherichia coli* O157:H7	RAC-290-12A	$<2.5 \times 10^1$	8.5×10^5	>99.9
		RAC-290-12B	$<2.5 \times 10^1$	8.5×10^5	>99.9
	Salmonella typhimurium	RAC-290-12A	$<2.5 \times 10^1$	3.1×10^6	>99.9
		RAC-290-12B	$<2.5 \times 10^1$	3.1×10^6	>99.9
	Listeria monocytogenes	RAC-290-12A	$<6.2 \times 10^1$	3.0×10^7	>99.9
		RAC-290-12B	$<5.2 \times 10^1$	3.0×10^7	>99.9
484276-14	*Staphylococcus aureus*	RAC-290-12A	1.5×10^3	4.0×10^6	99.9
		RAC-290-12B	7.0×10^2	4.0×10^6	99.9
		RAC-290-12C	2.3×10^3	4.0×10^6	99.9
	Klebsiella pneumoniae	RAC-290-12A	$<2.5 \times 10^1$	1.2×10^6	>99.9
		RAC-290-12B	$<2.5 \times 10^1$	1.2×10^6	>99.9
		RAC-290-12C	$<2.5 \times 10^1$	1.2×10^6	>99.9

MRID Number	Organism	Lot No.	Day	Total No. Surviving (CFU/carrier)	Parallel Control (CFU/carrier)	Percent Reduction
484276-10	*Staphylococcus aureus*	RAC-290-12A	15	$<2.0 \times 10^1$	1.2×10^6	>99.9
			22	3.4×10^1	1.6×10^5	99.9
			30	2.8×10^1	1.6×10^5	99.9
		RAC-290-12B	15	$<2.0 \times 10^1$	1.2×10^5	>99.9
			22	$<2.5 \times 10^1$	1.6×10^5	>99.9
			30	2.3×10^1	1.6×10^5	99.9
		RAC-290-12C	15	$<2.2 \times 10^1$	1.2×10^5	>99.9
			22	$<3.5 \times 10^1$	1.6×10^5	>99.9
			30	3.2×10^1	1.6×10^5	99.9
	Klebsiella pneumoniae	RAC-290-12A	15	$<2.0 \times 10^1$	1.1×10^6	>99.9
			22	3.0×10^1	1.1×10^6	99.9
			30	8.5×10^2	1.2×10^6	99.9
		RAC-290-12B	15	$<2.0 \times 10^1$	1.1×10^6	>99.9
			22	$<2.0 \times 10^1$	1.1×10^6	>99.9
			30	$<9.9 \times 10^1$	1.2×10^6	>99.9
		RAC-290-12C	15	$<2.0 \times 10^1$	1.1×10^6	>99.9
			22	$<2.0 \times 10^1$	1.1×10^6	>99.9
			30	$<1.0 \times 10^2$	1.2×10^6	>99.9
484276-13	*Escherichia coli* O157:H7	RAC-290-12A	15	$<2.0 \times 10^1$	2.7×10^5	>99.9
			22	$<2.0 \times 10^1$	2.8×10^5	>99.9
			30	6.7×10^1	2.9×10^5	99.9
		RAC-290-12B	15	$<2.0 \times 10^1$	2.7×10^5	>99.9
			22	$<2.0 \times 10^1$	2.8×10^5	>99.9
			30	$<2.0 \times 10^1$	2.9×10^5	>99.9
	Salmonella typhimurium	RAC-290-12A	15	$<2.0 \times 10^1$	4.3×10^5	>99.9
			22	$<2.0 \times 10^1$	1.9×10^5	>99.9
			30	$<3.7 \times 10^1$	3.0×10^5	>99.9
		RAC-290-12B	15	$<2.0 \times 10^1$	4.3×10^5	>99.9
			22	$<2.0 \times 10^1$	1.9×10^5	>99.9
			30	$<2.4 \times 10^1$	3.0×10^5	>99.9
	Listeria monocytogenes	RAC-290-12A	15	$<2.0 \times 10^1$	3.3×10^6	>99.9
			22	$<2.0 \times 10^1$	4.4×10^6	>99.9
			30	$<4.2 \times 10^1$	5.4×10^6	>99.9
		RAC-290-12B	15	$<2.0 \times 10^1$	3.3×10^6	>99.9
			22	$<2.0 \times 10^1$	4.4×10^6	>99.9
			30	$<2.0 \times 10^1$	5.4×10^6	>99.9

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Control Tiles
		Lot No. RAC-290-12A	Lot No. RAC-290-12B	Lot No. RAC-290-12C	
Hard, Non-Porous Surfaces					
484276-11	*Aspergillus niger*				10/10*
Test Date:	7 days	0/10	0/10	0/10	
9/14/2010	14 days	0/10	0/10	0/10	
	21 days	1/10	0/10	0/10	
	30 days	1/10	0/10	0/10	
484276-11	*Aspergillus niger*				10/10*
Test Date:	7 days	0/10	---	---	
10/19/2010	14 days	0/10			
	21 days	0/10			
	30 days	0/10			
484276-11	*Aspergillus niger*				10/10*
Test Date:	7 days	0/10	---	---	
10/20/2010	14 days	0/10			
	21 days	0/10			
	30 days	0/10			
Porous Surfaces					
484276-12	*Aspergillus niger*				10/10*
Test Date:	7 days	0/10	0/10	0/10	
11/17/2010	14 days	0/10	0/10	0/10	
	21 days	1/10	0/10	0/10	
484276-12	*Aspergillus niger*				10/10*
Test Date:	7 days	0/10	---	---	
12/01/2010	14 days	0/10			
	21 days	0/10			
484276-12	*Penicillium variable*				10/10*
Test Date:	7 days	0/10	0/10	0/10	
9/28/2010	14 days	0/10	0/10	0/10	
	21 days	0/10	0/10	0/10	
	30 days	0/10	0/10	0/10	

* At least 50% fungal growth on each untreated control tile was observed.

VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, KX-6207, as a sanitizer against the following microorganisms on hard, non-porous, non-food contact surfaces in the presence of a 5% organic soil load for a 5-minute contact time:

Staphylococcus aureus	MRID 484276-14
Klebsiella pneumoniae	MRID 484276-14
Escherichia coli O157:H7	MRID 484276-09
Salmonella typhimurium	MRID 484276-09
Listeria monocytogenes	MRID 484276-09

Bacterial reductions of at least 99.9 percent over the parallel control were observed within 5 minutes. At least one of the product lots tested against *Staphylococcus aureus* and *Klebsiella pneumoniae* was at least 60 days old at the time of testing. The parallel count demonstrated an average of at least 7.5×10^5 surviving organisms, which is the criterion set forth in ASTM 1153. Neutralization confirmation testing demonstrated that the neutralizer was effective and not detrimental to the test system. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data support the use of the product, KX-6207, as a sanitizer with residual activity against the following microorganisms on hard, non-porous, non-food contact surfaces in the presence of a 5% organic soil load:

Staphylococcus aureus	MRID 484276-10
Klebsiella pneumoniae	MRID 484276-10
Escherichia coli O157:H7	MRID 484276-13
Salmonella typhimurium	MRID 484276-13
Listeria monocytogenes	MRID 484276-13

Bacterial reductions of at least 99.9 percent over the parallel control were observed within 5 minutes on surfaces treated with the product up to 30 days prior. At least one of the product lots tested against *Staphylococcus aureus* and *Klebsiella pneumoniae* was at least 60 days old at the time of testing. Neutralization confirmation testing demonstrated that the neutralizer was effective and not detrimental to the test system. Purity controls were reported as pure. Sterility controls did not show growth.

3. The submitted efficacy data (MRID 484276-11) support the use of the product, KX-6207, as a fungistat/ mildewstat against *Aspergillus niger* on pre-cleaned, hard, non-porous surfaces. No growth was observed 30 days after treatment. [Note that repeat testing was conducted on one product lot.] Testing was conducted on 3 product lots. Untreated control tiles exhibited growth of *Aspergillus niger* on at least 50% of each untreated tile surface. Purity controls were reported as pure.

4. The submitted efficacy data (MRID 484276-12) do not support the use of the product, KX-6207, 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 lack of growth on the control carriers may indicate that the test conditions did not support sustained growth of *A. niger*. The Agency does not have a repeat testing policy; therefore repeated testing is unacceptable.

VII RECOMMENDATIONS

1. The proposed label claims that the product, RAC 100BL, is an effective sanitizer against the following microorganisms on pre-cleaned, hard, non-porous, non-food contact surfaces for a 5-minute contact time:

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

These claims are acceptable as they are supported by the submitted data.

2. 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. Furthermore, the residual tests were designed for residential uses. The use sites proposed on the current product label extend beyond residential sites.

3. On the proposed label, the statement "Avoid applications in areas with excessive water overspray or standing water" is present on page 2. Several of the use sites (namely drip pans, racks, troughs, and piping) function as reservoirs for water. This item must be addressed.

4. The proposed label claims that the product, RAC 100BL, inhibits the growth of molds up to 30 days on pre-cleaned, hard, non-porous surfaces. These claims are acceptable as they are supported by the submitted data. Residual fungistatic coating is not supported by the test method. The test method supports control, prevention, and inhibition of mold/mildew.

5. For residual sanitization of surfaces that are not touched, claims for continuous residual sanitizing must be removed or expanded to explain that surfaces may need to be cleaned/sanitized prior to additional applications of the product. As the wear component of the test is not included, the use sites must be limited to those areas where wear of the product from surfaces due to frequent touching is avoided.

6. On page 2 of the proposed label, expand the statement "Reapply RAC 100BL if the coating is visibly absent or disrupted" to read "Reapply RAC 100BL if the coating is visibly absent, disrupted, or frequently touched".

7. On page 2 of the proposed label, expand the statement "Avoid manual scrubbing or abrasion of the coated surfaces and aqueous cleaning products since these may remove the coating" to read "Avoid manual scrubbing or abrasion to include frequent touching of the coated surfaces and aqueous cleaning products to maintain residual sanitizing, since these may remove the coating".

8. The proposed label claims that the product, RAC 100BL, inhibits the growth of molds up to 14 days on pre-cleaned, porous surfaces. The Agency does not have a repeat testing policy; therefore repeated testing is unacceptable.

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

   - Identify the types of surfaces on which the product may be used (e.g., chrome, glass, stainless steel, vinyl).

   - On page 1 of the proposed label, change "RESDIUAL" to read "RESIDUAL", and expand to state on "untouched surfaces".

   - On page 2 of the proposed label, change "*Klebsiella pneumonie*" to read "*Klebsiella pneumoniae*."

   - On page 2 of the proposed label, change "Typhimurium" to read "typhimurium".

   - On page 2 of the proposed label, change "pneumonia" to read "pneumoniae".