UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 6, 2008

MEMORANDUM

Subject: Efficacy Review for Brace;
EPA Reg. No. 777-99; DP Barcode: D349258

From: Marcie Tidd, Microbiologist Marcie Tidd 3/6/08
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Applicant: Reckitt Benckiser, Inc.
Morris Corporate Center IV
399 Interpace Parkway
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Formulation from the Label:

Active Ingredient(s)	% by wt.
Alkyl (C_{14} 50%, C_{12} 40%, C_{16} 10%) dimethyl benzyl ammonium saccharinate	0.10%
Ethanol	58.00%
Other Ingredients	41.90%
Total	100.00%

I. BACKGROUND

The product, Brace, is an Agency-registered (Reg. No. 777-99) hospital/medical use disinfectant (bactericide, virucide, fungicide, and tuberculocide) and non-food contact surface sanitizer. The applicant is submitting supplemental data requested for *S. aureus* in a previous efficacy review (12/19/07 M. Tidd) to fulfill the Agency's repeat testing policy. Testing was conducted by Reckitt Benckiser Inc. Microbiology Laboratory (located at 1 Philips Parkway in Montvale New Jersey).

The data package contained a letter from the applicant's representative to the Agency (dated January 31, 2008), the Application for Pesticide form, the data matrix, a previous efficacy review (DP 345625) the proposed label (dated January 31, 2008), and one study (MRID 473370-01) with Statements of No Data Confidentiality and Good Laboratory Practice.

II. USE DIRECTIONS

The product is designed for disinfecting and sanitizing hard, non-porous surfaces such as bathtubs, bed frames, cat litter boxes, clean-up carts, desks, diaper pails, door knobs and handles, floors, garbage cans, glazed ceramic tile and porcelain, light switches, microwave exteriors, refrigerator exteriors, showers, sinks, telephones, toilets, wheelchairs, whirlpool interiors, and windows. The proposed label indicates that the product may be used on hard, non-porous surfaces, including those made of chrome, copper, crystal, enamel, glass, glazed ceramic, glazed porcelain, linoleum, metal, stainless steel, tin, and vinyl. Directions on the proposed label provided the following information regarding use of the product:

To Disinfect: Pre-clean surfaces prior to use. Hold can upright 6" to 8" from surface. Spray 2 to 3 seconds until covered with mist. Let stand for 5 minutes or 10 minutes to air dry. Rinse all food contact surfaces with potable water.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Microorganisms)

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step. These Agency standards are also presented in DIS/TSS-1.

Supplemental Recommendations

Antimicrobial agents which claim to be "one-step" cleaner-disinfectants, or cleaner-sanitizers, or agents to be used in the presence of organic soil, must undergo appropriate efficacy testing modified to include a representative organic soil of 5% blood serum. A suggested method to simulate antimicrobial treatment of dry inanimate surfaces is to add the blood serum 5% v/v (19mL bacterial inoculum with 1mL blood serum) to bacterial inoculum prior to carrier contamination and drying. Control data should be produced as described in Supplemental Recommendation 6 of DIS/TSS-2 to confirm the validity of this test with this modification. The suggested organic soil level is appropriate for simulation of lightly to moderately soiled surfaces. For highly soiled surfaces, a prior cleaning step should be recommended on the product label. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level (5 X 10^6 /ml) of conidia. These agency standards can be found in DIS/TSS-2.

IV. SUMMARY OF SUBMITTED STUDY

1. MRID 473370-01 "Disinfectant Efficacy Testing in the Presence of Organic Soil" by Kyle T. Smith. Study conducted by Reckitt Benckiser Microbiology Lab, Study Identification Number 2008-0006. Study completed January 28, 2008.

This test was conducted against *Staphylococcus aureus* (ATCC 6538) following the AOAC Germicidal Spray Products as Disinfectants test, 17th Edition 2000 and the Pesticide Assessment Guidelines Subdivision G: Product performance Section 91-2 (d). One lot of the product was tested (Formula 1056-010C (Batch 1056-080)). This batch was at least 60 days old at the time of testing. An organic soil load of 5% horse serum was present in the bacterial culture. The test substance was received ready to use. Sterile glass slide carriers were inoculated with 0.01 mL aliquots of the 48±2 hour old cultures, spread with a sterile inoculating loop, and dried for 40-42 minutes at 32.5-37.5C. Carriers were sprayed with the test agent for 2 to 3 seconds at a distance of 6-8", and remained in contact for 5 minutes at 22.6-22.7C. Following exposure, carriers were subcultured into 20 mL of Letheen Broth. Neutralized cultures were incubated for 46 hours, 8 minutes at 34.2-36.3C then examined for the presence or absence of visible growth. Controls included those for inoculum count, neutralizer effectiveness, viability, sterility, carrier count, and confirmation of the test organism.

V. RESULTS

MRID Number	Organism	Average Dried Carrier Count CFU/Carrier	No. Exhibiting Growth/Total No. Tested
			Formula 1056-010C Batch 1056-080
473370-01	*Staphylococcus aureus*	1.35×10^6	0/60

VI. CONCLUSIONS ON SUBMITTED DATA

1. The submitted data (MRID 473370-01) in conjunction with the previously submitted data (MRID 472464-01) **support** the use of the product, Brace (tested against Formula 1056-010B (Batch 1056-078), Formula 1056-010C (Batch 1056-080), and Formula 1056-054A (Batch 1056-079)), as a disinfectant against ***Staphylococcus aureus*** on hard, non-porous environmental surfaces in the presence of moderate organic soil, at full strength and room temperature with a contact time of 5 minutes.

   Results reported no growth on any of the 60 carriers for Formula 1056-010C Batch 1056-080. Carrier counts were at least 10^4 CFU/carrier. Other controls were acceptable for a valid test.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, Brace, is an effective hard surface hospital/medical disinfectant against the following organisms on hard, non-porous environmental surfaces at full strength and room temperature with a contact time of 5 minutes. These claims are **now acceptable.***

Staphylococcus aureus	ATCC 6538
Salmonella enterica	ATCC 10708
Pseudomonas aeruginosa	ATCC 15442
Vancomycin Resistant *Enterococcus faecalis*	ATCC 51299
Enterobacter aerogenes	ATCC 13048
Escherichia coli O157:H7	ATCC 43888
Listeria monocytogenes	ATCC 19115

*Previously, results reported growth on two of 60 carriers for Formula 1056-010C Batch 1056-080. The applicant indicated that the growth was due to contamination and tested an additional 10 carriers. This was determined to be inconsistent with the Agency's repeat testing policy, which requires re-testing of the entire lot of 60 carriers for a failure in 1 of 3 lots. With this most recent submission (MRID 473370-01), this requirement was satisfied.

2. Regarding the proposed label:

    a. Page 2 of the proposed label states that the product may be labeled as Hospital, Industrial, Institutional, or Professional Strength / Grade. These claims imply heightened efficacy and are a violation of 40 CFR 156.10, False or Misleading Statements. These claims must be removed from the proposed label.