UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 19, 2007

MEMORANDUM

Subject: Efficacy Review for Brace;
EPA Reg. No. 777-99; DP Barcode: D345265

From: Marcie Tidd, Microbiologist Marcie Tidd 12/19/2007
Product Science Branch
Antimicrobials Division (7510P)

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Thru: Michele E. Wingfield, Chief
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To: Adam Heyward PM 34 / Renae Whitaker
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Applicant: Reckitt Benckiser, Inc.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054

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 data to support claims against additional organisms at reduced contact times. Testing was conducted by both Reckitt Benckiser Inc. Microbiology Laboratory (located at 1 Philips Parkway in Montvale New Jersey) and ATS Labs (located at 1285 Corporate Center Drive in Eagan Minnesota).

The data package contained a letter from the applicant's representative to the Agency (dated September 28, 2007), the proposed label (dated 9/28/07), the last accepted label (dated 1/26/07) and ten studies (MRIDs 472464-01 through 472464-10) with Statements of No Data Confidentiality and Good Laboratory Practice for all.

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

Virucides

The effectiveness of virucides must be tested using virological techniques that simulate the conditions under which the product is intended for use. For products with intended use on dry, inanimate environmental surfaces, carrier tests that are variations of either the AOAC Use-Dilution Method (for liquid surface disinfectants) or the AOAC Germicidal Spray Products Test (for surface spray disinfectants) must be used to produce virucidal data. The virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface (petri dish, glass slide, steel cylinder, etc.) for a specified exposure period at room temperature. The virus must be assayed by an appropriate virological technique testing a minimum of four determinations for each dilution. The protocol for the viral assay must include viral recovery, cytotoxicity controls, and ID-50 values. Test results should be reported as the

reduction of the virus titer by the activity of the germicide (ID-50 of the virus control less the ID-50 of the test system) expressed as $\log_{10}$ and calculated by a statistical method. For virucidal data to be acceptable, the product must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. The calculated viral titers must be reported with the test results. Separate studies on two batches of product are required for each virus. These Agency standards are presented in DIS/TSS-7.

Supplemental Efficacy- Disinfectant Use on Pathogenic Fungi

Effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data derived from each of 2 samples representing 2 different batches using the AOAC Fungicidal Test. Performance requirements for this test: the highest dilution that kills all fungal spores is the minimum effective concentration. Alternatively, the AOAC Use Dilution Method, modified to conform with appropriate elements in the AOAC Fungicidal Test, may be employed. If the product is intended for use as a spray, the AOAC Germicidal Spray Products Test must be employed. The inoculum in the above tests must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 samples representing 2 different batches must be employed in the test. Performance standard for this test: killing of the test microorganism on all carriers is required. These agency standards can be found in DIS/TSS-6.

Note: As an interim policy, the Agency is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes* and *Aspergillus niger*. The Agency recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until the Agency determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

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 STUDIES

1. MRID 472464-01 "Disinfectant Efficacy Testing in the Presence of Organic Soil" by Kyle T. Smith. Study conducted by Reckitt Benckiser Microbiology Lab, Study Identification Number 2007-0041. Study completed July 20, 2007.

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). Three lots of the product were tested (Nos. Formula 1056-010B (Batch 1056-078), Formula 1056-010C (Batch 1056-080), and Formula 1056-054A (Batch 1056-079)). All batches were 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 47-53 minutes at 36.7-38.3C. 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 22.3-23.4C. Following exposure, carriers were subcultured into 20 mL of Letheen Broth. Neutralized cultures were incubated for 46 hours, 23 minutes to 66 hours, 39 minutes at 31.6-39.6C 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.

2. MRID 472464-02 "Disinfectant Efficacy Testing in the Presence of Organic Soil" by Kyle T. Smith. Study conducted by Reckitt Benckiser Microbiology Lab, Study Identification Number 2007-0042. Study completed July 20, 2007.

This test was conducted against *Salmonella enterica* (ATCC 10708) 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). Three lots of the product were tested (Nos. Formula 1056-010B (Batch 1056-078), Formula 1056-010C (Batch 1056-080), and Formula 1056-054A (Batch 1056-079)). All batches were 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 40-51 minutes at 36.2-37.9C. 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 22.3-23.4C. Following exposure, carriers were subcultured into 20 mL of Letheen Broth. Neutralized cultures were incubated for 64 hours, 35 minutes to 66 hours, 27 minutes at 35.8-38.7C 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.

3. MRID 472464-03 "Disinfectant Efficacy Testing in the Presence of Organic Soil" by Kyle T. Smith. Study conducted by Reckitt Benckiser Microbiology Lab, Study Identification Number 2007-0043. Study completed July 20, 2007.
This test was conducted against *Pseudomonas aeruginosa* (ATCC 15442) 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). Three lots of the product were tested (Nos. Formula 1056-010B (Batch 1056-078), Formula 1056-010C (Batch 1056-080), and Formula 1056-054A (Batch 1056-079)). All batches were 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 40-41 minutes at 31.6-33.5C. 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 22.3-23.4C. Following exposure, carriers were subcultured into 20 mL of Letheen Broth. Neutralized cultures were incubated for 46 hours, 5 minutes to 46 hours, 30 minutes at 32.0-35.1C 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.

4. MRID 472464-04 "Additional Microorganism Disinfectant Efficacy Testing in the Presence of Organic Soil" by Kelly Whitehead. Study conducted by Reckitt Benckiser Microbiology Lab, Study Identification Number 2007-0057. Study completed September 5, 2007.
This test was conducted against *Trichophyton mentagrophytes* (ATCC 9533) following the AOAC Germicidal Spray Products as Disinfectants test, 17th Edition 2000 and the Pesticide Assessment Guidelines Subdivision G: Product performance Section 91-2 (i). Three lots of the product were tested (Nos. Formula 1056-010B (Batch 1056-078), Formula 1056-010C (Batch 1056-080), and Formula 1056-054A (Batch 1056-079)). All batches were at least 60 days old at the time of testing. An organic soil load of 5% horse serum was present in the spore suspension. The test substance was received ready to use. Sterile glass slide carriers were inoculated with 0.01 mL aliquots of the cultures, spread with a sterile pipette tip, and dried for 40- minutes at 33.1-34.3C. 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 23.0-23.7C. Following exposure, carriers were subcultured into 20 mL of Letheen Broth. Neutralized cultures were incubated for 10 days at 29.8-32.8C 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.

5. MRID 472464-05 "Additional Microorganism Disinfectant Efficacy Testing in the Presence of Organic Soil" by Kelly Whitehead. Study conducted by Reckitt Benckiser Microbiology Lab, Study Identification Number 2007-0058. Study completed September 5, 2007.

This test was conducted against Vancomycin Resistant *Enterococcus faecalis* (ATCC 51299) following the AOAC Germicidal Spray Products as Disinfectants test, 17th Edition 2000 and the Pesticide Assessment Guidelines Subdivision G: Product performance Section 91-2 (i). Three lots of the product were tested (Nos. Formula 1056-010B (Batch 1056-078), Formula 1056-010C (Batch 1056-080), and Formula 1056-054A (Batch 1056-079)). All batches were 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 41 minutes at 34.3-35.1C. 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 23.0C. Following exposure, carriers were subcultured into 20 mL of Letheen Broth. Neutralized cultures were incubated for 47 hours, 3 minutes at 33.9-36.7C then examined for the presence or absence of visible growth. Controls included those for inoculum count, neutralizer effectiveness, viability, sterility, carrier count, resistance profile verification and confirmation of the test organism.

6. MRID 472464-06 "Additional Microorganism Disinfectant Efficacy Testing in the Presence of Organic Soil" by Kyle T. Smith. Study conducted by Reckitt Benckiser Microbiology Lab, Study Identification Number 2007-0059. Study completed July 20, 2007.

This test was conducted against *Enterobacter aerogenes* (ATCC 13048) following the AOAC Germicidal Spray Products as Disinfectants test, 17th Edition 2000 and the Pesticide Assessment Guidelines Subdivision G: Product performance Section 91-2 (i). Three lots of the product were tested (Nos. Formula 1056-010B (Batch 1056-078), Formula 1056-010C (Batch 1056-080), and Formula 1056-054A (Batch 1056-079)). All batches were 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 42 minutes at 34.7-35.1C. 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 23.0C. Following exposure, carriers were subcultured into 20 mL of Letheen Broth. Neutralized cultures were incubated for 47 hours, 20 minutes at 29.8-30.5C 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.

7. MRID 472464-07 "Additional Microorganism Disinfectant Efficacy Testing in the Presence of Organic Soil" by Kyle T. Smith. Study conducted by Reckitt Benckiser Microbiology Lab, Study Identification Number 2007-0060. Study completed July 20, 2007.

This test was conducted against *Escherichia coli* O157:H7 (ATCC 43888) following the AOAC Germicidal Spray Products as Disinfectants test, 17th Edition 2000 and the

Pesticide Assessment Guidelines Subdivision G: Product performance Section 91-2 (i). Three lots of the product were tested (Nos. Formula 1056-010B (Batch 1056-078), Formula 1056-010C (Batch 1056-080), and Formula 1056-054A (Batch 1056-079)). All batches were 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 56 minutes at 35.1-35.4C. 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 22.6-23.0C. Following exposure, carriers were subcultured into 20 mL of Letheen Broth. Neutralized cultures were incubated for 66 hours, 16 minutes at 33.9-36.7C 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.

Note: Additional data (conducted on 6/14/07) was also provided. The applicant indicated that this data is invalid because the organism used for testing was not verified to be the test system. No results were read or recorded from this test date.

8. MRID 472464-08 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" against Formula Number 667-180 (EPA Reg. No. 777-99) by Mary J. Miller. Study conducted by ATS Labs, Study Identification Number A04656. Study completed February 21, 2007, amended April 9, 2007.

This study was conducted against Influenza A Virus (H1N1) (Strain A Malaya/302/54, obtained from ATCC, #VR-98), using Rhesus monkey kidney (RMK) cells (obtained from ViroMed Laboratories, Inc.) as the host system. Two lots (Lot Nos. 960-028 and 960-030) of the product, identified as Formula 677-180, were tested according to ATS Protocol "REK01011707.FLUA" (copy provided). The product was received ready to use. Fetal bovine serum was added to the viral inoculum to create a 5% organic load. Films of virus were prepared by spreading 0.2 mL of virus inoculum over the bottoms of separate 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 19.0°C at a relative humidity of 40% until visibly dry (20 minutes). For each lot of product, carriers were sprayed with the test agent for 2 to 3 seconds at a distance of 6-8". Following the 30 second contact period, the virus-disinfectant mixture was neutralized by passing through individual Sephadex columns then serially diluted in Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multiwell culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated for 7 days at 36-38°C in a humidified atmosphere of 5-7% CO_2. Cultures were scored periodically over the 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, numbers control, infectivity, and neutralizer effectiveness. The 50% titration endpoint for infectivity ($TCID_{50}$) was determined by the method of Spearman Karber.

9. MRID 472464-09 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" against Formula Number 1056-010B and Number 1056-054A (EPA Reg. No. 777-99) by Mary J. Miller. Study conducted by ATS Labs, Study Identification Number A04657. Study completed February 27, 2007, amended April 9, 2007.

This study was conducted against Avian Influenza A Virus (H3N2) (Strain A Washington/897/80, obtained from ATCC, #VR-2072), using Rhesus monkey kidney (RMK) cells (obtained from ViroMed Laboratories, Inc.) as the host system. Two lots (Lot Nos. Formula 1056-010B (Batch 1056-078) and Formula 1056-054A (Batch 1056-079)) of the product were tested according to ATS Protocol "REK01011707. AFLU" (copy provided). The product was received ready to use. Fetal bovine serum was added to the viral inoculum to create a 5% organic load. Films of virus were prepared by spreading 0.2 mL of virus inoculum over the bottoms of separate 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 20.0°C at a relative humidity of 50% until visibly dry (20 minutes). For each lot of product, carriers were sprayed with the test agent for 2 to 3 seconds at a distance of 6-8". Following the 30 second contact period, the virus-disinfectant mixture was neutralized by passing through individual Sephadex columns then serially diluted in Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multiwell culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated for 7 days at 36-38°C in a humidified atmosphere of 5-7% CO_2. Cultures were scored periodically over the 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, numbers control, infectivity, and neutralizer effectiveness. The 50% titration endpoint for infectivity ($TCID_{50}$) was determined by the method of Spearman Karber.

10. MRID 472464-10 "AOAC Germicidal Spray Method" against Formula Numbers 1056-010B and 1056-054A, EPA Reg. No. 777-99 by Jill Ruhme. Study conducted by ATS Labs, Study Identification Number A04695. Study completed March 26, 2007.

This test was conducted against *Listeria monocytogenes* (ATCC 19117) according to ATS Protocol "REK01011707. GS.2" (copy provided). Two lots of the product were tested (Lot Nos. Formula 1056-010B (Batch 1056-078) and Formula 1056-054A (Batch 1056-079)). All batches were 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 48-54 hour old cultures, spread, and dried for 30 minutes at 36.0C at a 40% relative humidity. 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 22C. Following exposure, carriers were subcultured into 20 mL of Letheen Broth with 0.14% Lecithin and 1.0% Tween 80. Neutralized cultures were incubated for 48 ± 4 hours at 35-37C then examined for the presence or absence of visible growth. Controls included those for purity, neutralizer effectiveness, viability, sterility, and carrier count.

V. RESULTS

MRID Number	Organism	Average Dried Carrier Count CFU/Carrier	No. Exhibiting Growth/Total No. Tested		
			Formula 1056-010B Batch 1056-078	Formula 1056-010C Batch 1056-080	Formula 1056-054A Batch 1056-079
472464-01	*Staphylococcus aureus*	2.74×10^6	0/60	2/60, 0/10*	0/60
472464-02	*Salmonella enterica*	1.18×10^5	0/60	0/60	0/60
472464-03	*Pseudomonas aeruginosa*	2.68×10^6	0/60	0/60	0/60
472464-04	*Trichophyton mentagrophytes*	1.74×10^5	0/10	0/10	0/10
472464-05	Vancomycin Resistant *Enterococcus faecalis*	1.52×10^7	0/10	0/10	0/10
472464-06	*Enterobacter aerogenes*	6.9×10^5	0/10	0/10	0/10
472464-07	*Escherichia coli O157:H7*	2.46×10^6	0/10	0/10	0/10
472464-10	*Listeria monocytogenes*	1.11×10^6	0/10		0/10

*Two subculture tubes contained a contaminant (determined not to be the test organism) and an additional 10 carriers were tested.

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1mL)
			Formula 677-180 Batch 960-028	Formula 677-180 Batch 960-030	
472464-08	Influenza virus type A (H1N1)	10^{-1} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	$10^{5.5}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
			Formula 1056-010B Batch 1056-078	**Formula 1056-054A Batch 1056-079**	
472464-09	Avian influenza virus type A (H3N2)	10^{-1} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	$10^{4.75}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

VI. CONCLUSIONS ON SUBMITTED DATA

1. The submitted data (MRID 472464-01) **do not 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 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 is 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.

2. The submitted data **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 the following organisms 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.

Salmonella enterica	MRID 472464-02
Pseudomonas aeruginosa	MRID 472464-03
Vancomycin Resistant *Enterococcus faecalis*	MRID 472464-05
Enterobacter aerogenes	MRID 472464-06
Escherichia coli O157:H7	MRID 472464-07

   ***Note:** While data supports the use of the product against these organisms, **label claims for them will not be allowed until the applicant submits the required additional testing against *S. aureus*.**

   Testing for these organisms demonstrated complete killing on all carriers. All three product lots were at least 60 days old at the time of testing. Carrier counts exceeded 10^4 CFU/carrier (required for additional bacteria). Other controls were acceptable for valid tests.

3. The submitted data (MRID 472464-10) **support*** the use of the product, Brace (tested against Formula 1056-010B (Batch 1056-078) and Formula 1056-054A (Batch 1056-079)), as a disinfectant against ***Listeria monocytogenes*** 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.

   ***Note:** While data supports the use of the product against this organism, **label claims for it will not be allowed until the applicant submits the required additional testing against *S. aureus*.**

4. The submitted data (MRID 472464-04) **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 with fungicidal activity against ***Trichophyton mentagrophytes*** 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.

Testing demonstrated complete killing on all carriers. All three product lots were at least 60 days old at the time of testing. Carrier counts exceeded 10^4 CFU/carrier (required as an interim count for *T. mentagrophytes*). Other controls were acceptable for valid tests.

5. The submitted data (MRID 472464-08) **support** the use of the product, Brace (tested against Formula 677-180 (Batches 1960-028 and 960-030)), as a disinfectant with virucidal activity against **Influenza A Virus (H1N1)** (Strain A Malaya/302/54, ATCC #VR-98) on hard, non-porous environmental surfaces in the presence of moderate organic soil, at full strength and room temperature with a contact time of 30 seconds.

   Complete inactivation was seen at all dilutions. Dried virus controls exceeded 10^4 $TCID_{50}$/0.1mL. Controls were acceptable for a valid test.

6. The submitted data (MRID 472464-09) **support** the use of the product, Brace (tested against Formula 1056-010B (Batch 1056-078) and Formula 1056-054A (Batch 1056-079)), as a disinfectant with virucidal activity against **Avian Influenza A Virus (H3N2)** (Strain A Washington/897/80, ATCC #VR-2072) on hard, non-porous environmental surfaces in the presence of moderate organic soil, at full strength and room temperature with a contact time of 30 seconds.

   Complete inactivation was seen at all dilutions. Dried virus controls exceeded 10^4 $TCID_{50}$/0.1mL. Controls were acceptable for a valid test.

VII. RECOMMENDATIONS

A. Regarding the submitted data:

1. The proposed label claims that the product, Brace, is an effective hard surface 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 **currently unacceptable.***

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

*As indicated in the conclusions section, the applicant must **submit passing data for one lot of the product against *S. aureus***, as called for in the Agency's repeat testing guidelines. At such time that this data has been generated and accepted, these label claims will be acceptable. The applicant must also r**emove claims for 5 minute disinfection** until these criteria are met.

2. The proposed label claims that the product, Brace, is an effective hard surface disinfectant with fungicidal activity against ***Trichophyton mentagrophytes*** on hard, non-porous environmental surfaces at full strength and room temperature with a contact time of 5 minutes. These claims are **acceptable**, as they are supported by the submitted data.

3. The proposed label claims that the product, Brace, is an effective hard surface disinfectant with virucidal activity against **Avian Influenza A virus** (ATCC VR-2072 and VR-98) on hard, non-porous environmental surfaces at full strength and room temperature with a contact time of 5 minutes. These claims are **acceptable**, as they are supported by the submitted data. The applicant must also **list the strains tested** so that they are on record. ATCC # VR-2072 is not currently listed in the ATCC catalog, but was confirmed by ATCC technical support (12/19/07 phone call).

B. Regarding the proposed labeling:

1. On page 5 of the proposed label, the applicant claims that the product **kills germs in (30) seconds**. These claims are **unacceptable**. The product currently only meets criteria for "germ" claims at a 10 minute contact time, not 30 seconds. These **claims must be removed** from the label. (See http://www.epa.gov/oppad001/germs.htm)