UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 1, 2007

MEMORANDUM

Subject: Efficacy Review for CPPC Ultra Bleach 2;
EPA Reg. No. 70627-54; DP Barcode: D339856

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Applicant: Clorox Professional Products Company
c/o PS&RC; P.O. Box 493
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Formulation from the Label:

Active Ingredient(s)	% by wt.
Sodium Hypochlorite	6.15%
Other Ingredients	93.85%
Total	100.00%

I. BACKGROUND

The product, CPPC Ultra Bleach 2 (Reg. No. 67619-8), is an Agency-approved disinfectant (bactericide, virucide, fungicide, tuberculocide) and sanitizing rinse for use on hard, non-porous surfaces in household, commercial, institutional, food preparation, animal care, and hospital or medical environments. The applicant requested to amend the product registration to add claims for effectiveness as a disinfectant against *Acinetobacter baumannii* and Parainfluenza 1 virus. Studies were conducted at MicroBioTest, Inc., located at 105 Carpenter Drive in Sterling, VA 20164.

This data package contained a letter from the applicant to the Agency (dated April 18, 2007), Form 8570-34 (Certification with Respect to Citation of Data), Form 8570-35 (Data Matrix), two studies (MRID 471186-01 and 471186-02), Statements of No Data Confidentiality Claims for both studies, the last-accepted label (dated November 1, 2006), and the proposed label.

Note: The laboratory reports describe studies conducted for the product, F2001.0126. The applicant's letter to the Agency (dated April 18, 2007) states that the tested product, F2001.0126, is the product, CPPC Ultra Bleach 2, which is the subject of this efficacy report.

II. USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces such as appliance exteriors, bathtubs, cabinets, clothes hampers, counter tops, desks, diaper pails, door knobs, doors, drain boards, dressing carts, faucets, floors, furniture, garbage cans, kennels, lamps, light switch panels, litter boxes, patio furniture, plastic shower curtains, recycling bins, showers, sinks, telephones, toilets, toys, trash cans, and walls. The label indicates that the product may be used on glazed tile. The label also indicates that the product is not for use on aluminum, chipped enamel, silver, or steel. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Clean surface by removing gross filth. Add 2/3 cup of the product to 1 gallon of water (a 1:25 dilution). Wash, wipe, or rinse surfaces with water. Apply the use solution. Let stand 2 minutes. Rinse thoroughly and air dry.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

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

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 presented in DIS/TSS-1.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific 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 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results 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. These Agency standards are presented in DIS/TSS-7.

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 (5×10^6 /ml) of conidia. These agency standards can be found in DIS/TSS-2.

IV. SUMMARY OF SUBMITTED STUDIES

1. MRID 471186-01 "Use-Dilution Test – Supplemental Using *Acinetobacter baumannii* (ATCC 15308), Test Agent: F2001.0126," by Kathryn D. Kitchen. Study conducted at MicroBioTest, Inc. Study completion date – January 24, 2007. Laboratory Project Identification Number 320-422.

This study was conducted against *Acinetobacter baumannii* (ATCC 15308). Two lots (Lot Nos. CGBB1 and CGBB2) of the product, F2001.0126, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. Use solutions were prepared by adding 1 part product to 24 parts 100±2.9% ppm AOAC synthetic hard water (a 1:25 dilution). Heat-inactivated fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed in a 48-54 hour old suspension of the test organism, at a ratio of 20 carriers per 20 mL broth. The carriers were dried for 20 minutes at 37±2°C. Each carrier was exposed to 10 mL of the use solution for 2 minutes at 22°C. After exposure, the carriers were transferred to Letheen Broth containing 0.2% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 37±2°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for dried carrier counts, sterility, viability, neutralizer effectiveness, bacteriostasis, and confirmation of the challenge microorganism.

Note: A study initiated on August 21, 2006 was invalidated because the incorrect dilution of the product was used. Test results for this study were not provided in the laboratory report.

2. MRID 471186-02 "Virucidal Efficacy Test, Parainfluenza virus (Sendai), Test Agent: F2001.0126," by Lauren A. Blaszak. Study conducted at MicroBioTest, Inc. Study completion date – December 5, 2006. Laboratory Project Identification Number 320-435.

This study was conducted against Parainfluenza 1 virus (ATCC VR-907; Strain Sendai), using embryonated chicken eggs (obtained from B&E Eggs) as the host system. Two lots (Lot Nos. CGBB1 and CGBB2) of the product, F2001.0126, were tested according to MicroBioTest Protocol, "Virucidal Efficacy Test, Parainfluenza virus (Sendai)," dated July 26, 2006. Use solutions were prepared by adding 1 part product to 24 parts 100±2.9% ppm AOAC synthetic hard water (a 1:25 dilution). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried at ambient temperature. For each lot of product, separate dried virus films were treated with 2.0 mL of the use solution for 5 minutes at 22°C. After exposure, the plates were treated with 2.0 mL newborn calf serum containing 0.01% sodium thiosulfate. The mixture was scraped from the surface of the dish with a cell scraper. Ten-fold serial dilutions were prepared, using Earle's Balanced Salt Solution. Embryonated eggs were inoculated intra-allantoically in quadruplicate with 0.2 mL of the dilutions. The eggs were incubated for 2-4 days at 36±2°C. Post-incubation, the eggs were candled and then kept at 2-8°C overnight. Afterwards, the allantoic fluid was

harvested and stored at -10°C until assay. The samples were assayed for the presence of replicating virus using a hemagglutination assay. Controls included those for host viability/ media sterility, plate recovery, toxicity, toxicity-related viral interference, and neutralizer effectiveness. The 50% embryo lethal dose/ embryo infectious dose per mL (ELD/EID_{50}/mL) was determined using the method of Reed and Muench.

Note: A study initiated on September 1, 2006 was invalidated because the incorrect virus strain was used. Test results for this study were not provided in the laboratory report.

Note: The laboratory report includes a "Confidentiality" clause on page 24, which restricts the reporting of data to the public.

V. RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Dried Carrier Count (CFU/ carrier)
		Lot No. CGBB1	Lot No. CGBB2	
471186-01	*Acinetobacter baumannii*	0/10	0/10	1.1×10^5

MRID Number	Organism	Results			Plate Recovery Control
			Lot No. CGBB1	Lot No. CGBB2	
471186-02	Parainfluenza 1 virus	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$\geq 10^{7.50}$ ELD/EID_{50}/ mL
		ELD/EID_{50}/mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	

VI. CONCLUSIONS

1. The submitted efficacy data (MRID 471186-01) support the use of a 1:25 use solution of the product, CPPC Ultra Bleach 2 (also known as F2001.0126), as a disinfectant against *Acinetobacter baumannii* on hard, non-porous surfaces in the presence of 100 ppm hard water and a 5% organic soil load for a contact time of 2 minutes. No growth was observed in the subcultures of the required number of carriers tested against the required number of product lots. Dried carrier counts were at least 10^4. Neutralizer effectiveness testing showed positive growth of the microorganism. Viability controls were positive for growth. Sterility controls did not show growth. Bacteriostasis streaks exhibited no growth.

2. The submitted efficacy data (MRID 471186-02) support the use of a 1:25 use solution of the product, CPPC Ultra Bleach 2 (also known as F2001.0126), as a disinfectant with virucidal activity against Parainfluenza 1 virus on hard, non-porous surfaces in the presence of 100 ppm hard water and at least a 5% organic soil load for a contact time of 5 minutes. Plate recovery counts were at least 10^4. Complete inactivation (no growth) was indicated in all dilutions tested.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, CPPC Ultra Bleach 2, is an effective disinfectant on hard, non-porous surfaces against the following microorganisms, without a pre-cleaning step, for the listed contact times at a 1:25 dilution:

Acinetobacter baumannii	2 minutes
Parainfluenza 1 virus	5 minutes

These claims are acceptable, as the provided data support these claims.

2. The proposed label presents new marketing claims and new detail for the organisms against which the product is effective. In addition, some information on the proposed label has been re-ordered or re-organized. The content of the entire label and Service Bulletin were reviewed. The applicant must make the following changes:

- On page 3 of the proposed label [first column] delete the claim "Especially recommended for Food Service Germicidal Applications." The product may bear label claims for a germicidal disinfectant, however the product was not tested against enough organisms under food-contact sanitization to qualify as a germicide for this use.

- On page 3 of the proposed label [third column], remove the following marketing claim: "This product is unbeatable."

- On page 5 of the proposed label, remove "*Campylobacter jejuni*" from the list of bacteria in the General Use Organism Table. This organism was not listed on the last-accepted label (dated November 1, 2006), for hard, non-surface disinfectant applications. The Data Matrix identifies an efficacy study for *Campylobacter jejuni* (MRID 433034-02; food contact) but this study does not support disinfectant claims.

- On page 5 of the proposed label, remove "*Klebsiella pneumoniae*" from the list of bacteria in the General Use Organism Table. This organism was not listed on the last-accepted label (dated November 1, 2006), for hard, non-surface disinfectant applications, and no such data is referenced in the matrix.

- On page 5 of the proposed label, remove "*Listeria monocytogenes*" from the list of bacteria in the General Use Organism Table. This organism was not listed on the last-accepted label (dated November 1, 2006), for hard, non-surface disinfectant applications. The Data Matrix identifies an efficacy study for *Listeria monocytogenes* (MRID 433034-02; food contact); however, it does not support disinfectant claims.

- On page 5 of the proposed label, change "Cytomelagovirus" to read "Cytomegalovirus."

- On page 5 of the proposed label, add another * to the following organisms listed in the General Use Organism Table: *Mycobacterium bovis*, Adenovirus type 2, Norwalk virus, and Rhinovirus. The contact time should be identified as 5 minutes, not 2 minutes.

Change "Norwalk virus" to "Norovirus", include the tested surrogate Feline Calicivirus in parentheses.

- On page 5 of the proposed label, add the appropriate asterisks to the following organisms listed in the General Use Organism Table: *Candida albicans*, *Aspergillus niger*, *Trichophyton mentagrophytes*, and HIV-1 (two places). The contact time must be identified.

- On page 6 of the proposed label, add a description of the composition of surfaces on which the product may be used (e.g., stainless steel, chrome, glass, vinyl) to satisfy DIS/TSS-15 standards.

- On page 8 of the proposed label, the directions for disinfecting baby furniture and toys specify a 2-minute contact time. A 5-minute contact time is necessary to disinfect against viruses, this must be indicated.

- On page 9 of the proposed label, revise the following claim so that it is accurate and complete: "Safe for most color-fast 9."

- On page 11 of the proposed label under the application for wipe cloths, change "Add 2 ½ pumps of this product" to read "Add 2 pumps of this product."

- On page 12 [Service Bulletin], delete one of the references to *Pseudomonas aeruginosa* in the "For Sanitizing Hospital Laundry" section.

- On page 13 [Service Bulletin], delete one of the references to *Pseudomonas aeruginosa* in the "For Disinfecting Hospital Laundry" section.

- On page 23 [Service Bulletin], correct the contact time in the "Special Instructions . . ." section. The product is effective against HBV and HCV at a 5-minute contact time, not a 2-minute contact time. The product is effective against HIV-1 at a 2-minute contact time.

3. The proposed label claims that the product is an effective disinfectant/ sanitizer in laundry use applications against Hepatitis B virus. The Data Matrix does not identify an efficacy study for Hepatitis B virus in laundry use applications. The applicant needs to update the Data Matrix or remove these claims from the label.