UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

December 13, 2008

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 67619-8, CPPC Ultra Bleach 2;
DP Barcode: 359558

From: Tajah L. Blackburn, Ph.D., Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)
12/15/08

Thru: Michele Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Emily Mitchell PM 32/ Wanda Henson
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: The Clorox Company
c/o PS & RC
PO Box 493
Pleasanton, CA 94566-0803

Formulations from 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 (EPA Reg. No. 67619-8) is a registered hospital disinfectant (bactericide, virucide, and fungicide, tuberculocide), food contact sanitizer for use in hospital rooms, sick rooms, dental offices, health clubs, kennels, diners, kitchens, patient rooms, hotels/motels and bathrooms. In the current submission, the registrant requests to add claims for effectiveness against *Phytophthora ramorum*, Community Acquired Methicillin Resistant *Staphylococcus aureus* (CA-MRSA), *Escherichia coli* with extended spectrum beta-lactamase resistance, and *Clostridium difficile* spores. Efficacy data was generated at (1) Oregon State Laboratory located in Corvallis, OR, (2) ATS Labs located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121, and (3) Centre for Research on Environmental Microbiology, University of Ottawa, 451 Smyth Road, Ottawa, Ontario, Canada K1H 8M5.

The data package contained a letter from the registrant (dated November 24, 2008), EPA Form 8570-34, Data Matrix (EPA Form 8570-35), Statement of No Data Confidentiality, five efficacy studies (MRID No. 476085-01 thru -06), and the proposed label.

Note: The letter from the registrant further states that "we [CPPC] are submitting Volume VI entitled 'Supplemental Information in Support of Efficacy against *Clostridium difficile*' which contains the infection-reduction claims and all of the supporting published data to support the claims. It is in a single volume to facilitate circulation and review. No infection-reduction language appears on the master label, as we are not requesting formal consideration of the claim with the submission. Rather, it is submitted at this time for early review. We will formally ask for review of the infection-reduction claim upon completion of the Agency review and acceptance of the newly submitted data and label."

II USE DIRECTIONS

The product is for use on garbage disposals/cans, sinks, appliances, stoves, countertops, walls, floors, kennels, doorknobs, clothes hampers, dressing carts, high chairs, and diaper pails composed glazed porcelain, vinyl, glazed tile, plastic, glass, linoleum, and painted woodwork. Directions on the proposed label provided the following instructions for the preparation and use on the product as a disinfectant:

Bacteria: First clean surface by removing gross filth. Prepare a 2400 ppm available chlorine solution. Thoroughly wet surface with the solution and allow to remain on the surface for 2 minutes. Rinse with clean water and dry.

Clostridium difficile spores: Use 1 part bleach to 9 parts water to achieve a 1:10 dilution (~5000 ppm available chlorine) before use. Clean hard, non-porous surfaces by removing gross filth [loose dirt, debris, blood/bodily fluids, etc.]. Apply 1:10 solution and let stand for 10 minutes.

Controlling the Spread of *Phytophthora ramorum*: Add 1 gallon of this product to 1000 gallons (~50 ppm available chlorine) of drafted water. Prepare the mixture at least 5 minutes prior to application for dust abatement, fire suppression, and cleaning vehicles and logging, road building, and maintenance equipment.

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.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV SYNOPSIS OF SUBMITTED EFFICACY STUDIES

1. MRID No. 476085-01, "The Effectiveness of Sodium Hypochlorite Against *Phytophthora ramorum*" by Dr. Everett Hansen and Dr. Paul Reeser. Study Completion Date—September 25, 2008. Project Number not assigned.

Note: The submitter of these studies was neither the sponsor of these studies nor conducted them, and does not know whether they have been conducted in accordance with 40 CFR 160.

The study was conducted using *Phytophthora ramorum* chlamydospores 2018.1 (source not identified) using deionized water in Test #1 and creek water in Test #2. Chlamydospore suspension was prepared by removing ten plugs (6 mm dia) from 57 day-old culture of *P. ramorum* 2018.1 grown on ⅓ V8 agar (triple colony plate), add to 15 ml sterile deionized water (charcoal filtered). Cultures were homogenized for 20 seconds, and then strained through fine stainless steel sieve to make a total of 30 ml. H/2 agar plates were inoculated with four 0.1 ml drops of chlamydospore suspension. All spores were counted in one drop to determine a minimum of 100 germinated and ungerminated chlamydospores in non-overlapping transects. Test solutions (2:100, 2:1000, and 2: 100,000) were prepared using 6.15% (Test 1) and 6% (Test 2) sodium hypochlorite. Five (5) ml of test solution and 5 ml of chlamydospores were placed in a sterile glass tube, and vortex mixed. At each time interval (5, 10, 20 and 80 minutes), suspension is vortex mixed, and one (1) ml is removed and diluted in 9 ml of PBG. The diluted test suspension is vacuum-filtered. The filter membrane is removed, and placed face down on H/2 agar plates, and incubated at 21°C (in the dark). With the membrane

in place, 100 germinated and ungerminated chlamydospores were counted on non-overlapping transects using 100X compound microscope.

Note: Test #2 included creek water to simulate what would happen in a real-world situation where water was drafted from streams for fire and dust abatement and treated with Clorox.

2. MRID No. 476085-02, "AOAC Use Dilution Method" against Community Acquired Methicillin Resistant *Staphylococcus aureus* (NARSA NRS 123) (Genotype USA400) and Community Acquired Methicillin Resistant *Staphylococcus aureus* (NARSA NRS384) (Genotype USA300) by Becky Lien. Study completion date—July 18, 2008. Project Number A06280.

This test was conducted against Community Associated Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) (NARSA NRS 123, Genotype USA400, and Community Associated Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) (NARSA NRS 384, Genotype USA300, both strains obtained from NARSA contracts Administration at Focus Technologies, Inc., following ATS protocol CX21021208.UD.1 (included). Two lots of the product, CPPC Ultra Bleach 2, were tested (Lot Nos. 08CGB1 and 08CGB2. Organic soil load, at 5%, was incorporated into the test. The test substance was prepared using ⅔ cup of test substance per gallon of 100 ppm AOAC Synthetic Hard Water. Sterile penicylinders were immersed for 15 minutes in a 48-54 hour old broth culture of the test organism, at a ratio of 1 carrier per 1.0 ml broth. The penicylinders were then dried on filter paper in a sterile Petri dish at 35-37°C for 40 minutes at a 40% relative humidity. For each prepared test substance, 10 contaminated and dried carriers were individually transferred at staggered intervals to individual tubes containing 10 ml of the test substance (at the use dilution and exposed for two minutes at 20±1°C). Following exposure, each exposed carrier was then transferred by hook needle at identical staggered intervals to 10 ml of Letheen broth with 0.1% sodium thiosulfate. Carriers were transferred from primary subculture tubes into individual secondary subculture tubes containing 10 ml of Letheen broth with 0.1% sodium thiosulfate. Neutralized subcultures were incubated for 45 hours at 35-37°C. Following incubation, subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability control, neutralization confirmation, and carrier counts.

Note: ATS Labs verified that the organisms were resistant by performing a Kirby Bauer Susceptibility assay on the day of testing. Briefly, the organism was subcultured onto a BAP plate and was incubated for approximately 24 hours at 35-37°C. Following incubation, a suspension of the test organism equal to a 0.5 McFarland Standard was made in 0.85% sterile saline. The suspension was streaked onto Mueller Hinton agar. An oxacillin disc was placed in the center of the inoculated Mueller Hinton plate. The plate was inverted and incubated for 24 hours at 35-37°C. Following incubation, the zone of inhibition was measured using a calibrated caliper. A control organism, *Staphylococcus aureus* (ATCC 25923), was run concurrently with the test organism to confirm the validity of the assay. The interpretation of the zone of inhibition is based on established performance standards of the Clinical and Laboratory Standards Institute (CLSI).

Test History: Testing was performed on May 19, 2008, which resulted in CPPC Ultra Bleach 2, F2001.0126, Batch 08CGB1 showing growth in 1 of the 10 tubes when tested

against Community Acquired Methicillin Resistant *Staphylococcus aureus*-CA-MRSA (NARSA NRS384) (Genotype USA300) and CPPC Ultra Bleach 2, F2001.0126, and Batch 08CGB2 showing growth in 1 of the 10 tubes when tested against Community Acquired Methicillin Resistant *Staphylococcus aureus* CA-MRSA (NARSA NRS 123) (Genotype USA400). Testing was repeated on June 12, 2008, to test for potential false positives.

Test Organism	Date Performed	Result
Community Acquired Methicillin Resistant *Staphylococcus aureus*-CA-MRSA (NARSA NRS384) (Genotype USA300)	5/19/08	2.89 x10^6 CFU/carrier
	6/12/08	8.4 x 10^6 CFU/carrier
Community Acquired Methicillin Resistant *Staphylococcus aureus* CA-MRSA (NARSA NRS 123) (Genotype USA400)	5/19/08	2.61 x 10^6 CFU/carrier
	6/12/08	7.7 x 10^6 CFU/carrier

Note: Protocol deviations/amendments were documented.

3. MRID No. 476085-03, "AOAC Use-Dilution Method" against *Escherichia coli* (with extended spectrum beta-lactamase resistance (ATCC BAA-196) by Jill Ruhme. Study completion date—October 30, 2008. Project Number A06656.

This test was conducted against *Escherichia coli* with extended spectrum beta-lactamase resistance (ATCC BAA-196) following ATS protocol CX18070208.UD.1 (protocol included). Two lots (Lot Nos. 08CGB1 and 08CGB2) of the product, CPPC Ultra Bleach 2, were tested. Organic soil load, at 5%, was incorporated into the test. The test substance was prepared using ⅔ cup of test substance per gallon of 100 ppm AOAC Synthetic Hard Water. Sterile penicylinders were immersed for 15 minutes in a 48-54 hour old broth culture of the test organism, at a ratio of 1 carrier per 1.0 ml broth. The penicylinders were then dried on filter paper in a sterile Petri dish at 35-37°C for 40 minutes at a 20.8% relative humidity. For each prepared test substance, 10 contaminated and dried carriers were individually transferred at staggered intervals to individual tubes containing 10 ml of the test substance (at the use dilution and exposed for two minutes at 20.0°C). Following exposure, each exposed carrier was then transferred by hook needle at identical staggered intervals to 10 ml of Letheen broth with 0.1% sodium thiosulfate. Neutralized subcultures were incubated for 48±4 hours at 35-37°C. Following incubation, subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability control, neutralization confirmation, and carrier counts.

Test Organism	Date Performed	Result
Escherichia coli with extended beta-lactamase resistance (ATCC BAA-196)	9/2/08	3.4 x 10^6 CFU/carrier

Note: ATS labs used the AB BIODISK Etest Method to verify the antimicrobial susceptibility pattern of *Escherichia coli* Extended Spectrum Beta-Lactamase (ESBL). The organism was grown on TSA with 5% sheep blood and used to make a suspension equal to 0.5 McFarland standard in 0.85% sterile saline. The test organism suspension was streaked onto a Mueller Hinton agar plate using a sterile swab. The Etest strip containing Cefotaxime (CT) and Cefotaxime + Clavulanic acid (CTL) and the Etest strip containing Ceftazidime (TZ) and Ceftazidime + Clavulanic (TZL) were both placed on the inoculated Mueller Hinton agar plate. The plates were incubated for 16-18 hours at 35-37°C. Following incubation, the minimum inhibitory concentration (MIC) values for CT, CTL, TZ, and TZL were read. Two quality control strains were run concurrently with the test organism to confirm the validity of the assay. *Escherichia coli* (ATCC 35218) served as the negative control and *Klebsiella pneumoniae* (ATCC 700603) served as the positive control for this test. The interpretation of the MIC values for the test organism was determined using the Reading and Interpretation section included in the attached reference for AB BIODISK Etest Method. The quality control results were determined using the specifications for the Etest ESBL CT/CTL and TZ/TZL strips.

Organism	MIC Value Cefotaxime (CT)	MIC Value Cefotaxime and Clavulanic acid (CTL)	MIC Value Ceftazidime (TZ)	MIC Value Ceftazidime and Clavulanic acid (TZL)	Interpretation Results
QC Organism: *Escherichia coli* (ATCC 35218)	<0.25 µg/ml	0.016 µg/ml	<0.5 µg/ml	<0.125 µg/ml	Negative ESBL
QC Organism *Klebsiella pneumoniae* (ATCC 700603)	1.0 µg/ml	0.25 µg/ml	24 µg/ml	0.38 µg/ml	Positive ESBL
Escherichia coli (ESBL) (ATCC BAA-196)	0.25	0.125 µg/ml	32 µg/ml	0.38 µg/ml	Positive ESBL

4. MRID No. 476085-04, "Quantitative Carrier Test Tier 2 (QCT-2) to Assess the Sporicidal Activity of a Liquid Microbiocide against Clostridium difficile (ATCC 43598)" using CPPC Ultra Bleach 2, by Justo Perez, Ph.D. Study completion date—November 13, 2008. Laboratory Project Number CREM-2008-07-21-QCT-2-CD.

Note: This study was conducted in accordance with the US Environmental Protection Agency Good Laboratory Practice Standards, 40 CFR 160 with the following exceptions:

- Quality Assurance support was provided by Clorox and Clorox's SOP were followed for QA activities. A master schedule for this study was not maintained.
- An approved SOP was not available for the receipt, storage, and distribution of test substance samples however documentation was maintained for all these items.
- Approved SOPs were not available for all pieces equipment. Calibration and maintenance activities for equipment (e.g. pipettes) was routinely conducted but not specifically documented.

- There were few instances when data entries were not recorded promptly or data entries were not initiated and dated at the time of entry.

This test was conducted against *Clostridium difficile* spores (ATCC 43598) following the Standard Quantitative Disk Carrier Test Method for Determining the Bactericidal, Virucidal, Fungicidal, Mycobactericidal and Sporicidal Activities of Liquid Chemical Germicides (ASTM International E2197-02). Three lots (Lot Nos. 08CGB1, 08CGB2, and 08CGB3- 60 day aged lot) of the product, CPPC Ultra Bleach 2, were tested. Test samples were shipped in three 1 L white plastic bottles. Testing of the samples at CREM by the DPD yielded: 08CGB1=6.00%, 08CGB2=6.03% and 08CGBB (60 days aged) = 6.45% as sodium hypochlorite. Use dilutions (1:10) of the test sample were prepared by mixing 0.2 ml of the test sample with 1.8 ml of 400 ppm sterile hard water in a sterile cryovial. This test dilution was found to have approximately 6000 ppm as total chlorine and was kept at 20±0.5°C. This working dilution was tested for sporicidal activity within 3 hours of dilution. **The spore suspension was prepared using a process developed at CREM and the details are proprietary at this stage.** Briefly, the spores were obtained in a peptone-salts liquid medium, incubated anaerobically at 36.5±0.5°C, collected, cleaned, heated at 70°C for 10 minutes, and kept in water suspension at 3±1°C. From the spore stock suspension, test organism (~2.5 x 10^8 CFU/ml) was prepared with 200 µl of soil load approximately 2 x 10^6 CFU/10 µl, 10 µl of BSA, 40 µl of mucin, and 14 µl of yeast extract stock (dilution factor= 0.68). This suspension was mixed well, and used for carrier contamination. Fifteen (15) sterile carrier disks were placed in a sterile glass Petri dish. Ten microliters of the test inoculum was placed at the center of each disk with a positive displacement pipette. With the Petri plate lid removed, the disks were left in the hood to dry for ~60 minutes. After the disks had dried, the Petri plate was transferred to a dessicator connected to the vacuum line. The vacuum was applied to allow the disks to dry for an additional 2 hours. These contaminated disks were used for the disinfection test. The relative humidity and air temperature in the hood was read using a thermo-hygrometer. The dried carriers, 13/disinfectant sample, were placed (with the contaminated side facing up) one each on the bottom of a sterile polycarbonate vial. Three of the disks were used as controls and the rest used for the disinfection test. The disinfection test was conducted in two groups of 3 and one group of 4 vials each time to ensure that the contact time could maintained. Each one of the ten test disks with the dried inoculum was overlaid with 50 µl of the test substance at 30 seconds intervals, and then all samples were returned to the constant temperature incubator. The control disks received an equivalent volume of 400 ppm hard water. At the end of 9 minutes, the vials were returned to the hood. At the end of 9.5 minutes, each vial received 10 ml of neutralizer and the vial was vortexed for 30 seconds to elute the material from the disk. The eluate from each vial was passed through a 47 mm diameter membrane (0.22 µm pore diameter). The vial and the disks were rinsed four times with 10 ml volumes of PBS and the washes were also passed though the same filter. For control carriers, one ml of the eluate was immediately removed, collected in a sterile vial and then subjected to six ten-fold dilutions in PBS. The dilutions -4, -5, and -6 were separately passed through membrane filters. The filter membranes were placed on the surface of BHIS agar plates (and incubated in anaerobic chamber at 36.5±1°C; the plates were first examined at the end of 48 hours of incubation and at the end of five days of incubation to count and record the number of colonies). Digital camera pictures of the plates were taken for a permanent record. Controls included those for purity, sterility, neutralization confirmation, and carrier counts.

Protocol deviations

(1) The concentration of sodium thiosulfate in the neutralizer was mistakenly given as 0.1%. It is 1% (w/v) because of the relatively high level of the active in the samples tested in the study. The neutralizer also contained 0.1% (w/v) Tween-80.
(2) Lots 08CGB1 and 08CGB2 were tested 20-30 minutes after the 3 hour deadline. When the test samples were analyzed for chlorine content up to 6 hours after preparation only negligible differences in the concentration of available chlorine were found. It is not believed to have affected the results.

MRID Nos. 476085-05 and -06 contain the proposed infection-reduction claims and supporting published data to support the claims. This information was submitted at this time for early review. In absence of finalized guidance for infection reduction claims, the provided data will not be included in the current review. The information will be retained for future review once guidance has been determined.

V RESULTS

MRID No. 476085-01
Test #1 September 11, 2008

Interval	Treatment	Chlamydospore Count		Colony Count
		Germinated	Ungerminated	
5 minutes	DI water	17	83	160
	0.5 X PBG	20	88	167
	1:100000	Not done	--	134
	1:1000	0	100	0
	1:100	0	100	0
10 minutes	DI water	10	90	115
	0.5 X PBG	26	74	226
	1:100000	28	82	126
	1:1000	0	100	0
	1:100	0	100	0
20 minutes	DI water	21	79	148
	0.5 X PBG	23	77	134
	1:100000	24	76	163
	1:1000	--	--	1
	1:100	--	--	0
80 minutes	DI water	9	81	145
	0.5 X PBG	14	86	131
	1:100000	17	83	132
	1:1000	--	--	0
	1:100	--	--	0

	DI water	0.5x PBG	Treatment		
			1:100000	1:1000	1:100
Average Colony Count	142[3]	165[3]	139[3]	0	0
Percent Germination	17	25	24	0	0
Estimated Chlamydospores[1]	835	660	580		
Expected Chlamydospores[2]	1100	1100	1100	1100	1100

[1]Based on Colony count X percent germination.
[2]Based on counts of 0.1 ml drops of chlamydospore suspensions.
[3]Probable undercount as chlamydospores are very crowded, with many clumps of 2 or 3.

Test #2, September 18, 2008

Interval	Treatment	Chlamydospore Count	
		Plate 1	Plate 2
5 minutes	0.5x PBG	149	121
	0.5x OCW	136	140
	1:1000 0.5x OCW	0	0
	1:10000	18	18
	1:1000	0	0
	1:100	0	0
10 minutes	0.5x PBG	160	132
	0.5x OCW	157	154
	1:1000 0.5x OCW	0	0
	1:10000	18	24
	1:1000	0	0
	1:100	0	0
20 minutes	0.5x PBG	137	167
	0.5x OCW	191	193
	1:1000 0.5x OCW	0	0
	1:10000	11	15
	1:1000	0	0
	1:100	0	0
80 minutes	0.5x PBG	164	197
	0.5x OCW	153	141
	1:1000 0.5x OCW	0	0
	1:10000	11	15
	1:1000	0	0
	1:100	0	0

	Test Solution					
	0.5x PBG	0.5x OCW	1:1000 Clorox in 0.5x OCW	1:10000 Clorox	1:1000 Clorox	1:100 Clorox
Average Colony Count	153[2]	158[2]	0	16	0	0
Expected Colonies[1]	338	338	338	338	338	338

[1]Based on counts of 0.1 ml drops of chlamydospore suspension
[2]Probable undercount as chlamydospores are very crowded, with many clumps of 2 or 3.

MRID No. 476085-02

Test Substance	Test Organism	Date Performed	Sample Dilution	Number of Carriers	
				Exposed	Showing Growth
Lot No. 08CGB1	CA-MRSA (NARSA NRS 123) (Genotype USA400)	5/19/08	⅔ cup per gallon	1°=10 2°=10	1°=0 2°=0
	CA-MRSA (NARSA NRS384) (Genotype USA300	5/19/08		1°=10 2°=10	1°=0 2°=1
		6/12/08		1°=10 2°=10	1°=0 2°=0
Lot No. 08CGB2	CA-MRSA (NARSA NRS 123) (Genotype USA400)	5/19/08		1°=10 2°=10	1°=0 2°=1
		6/12/08		1°=10 2°=10	1°=0 2°=0
	CA-MRSA (NARSA NRS384) (Genotype USA300	5/19/08		1°=10 2°=10	1°=0 2°=0

MRID No. 476085-03

Test Substance	Test Organism	Date Performed	Sample Dilution	Number of Carriers	
				Exposed	Showing Growth
Lot No. 08CGB1	*Escherichia coli* with extended spectrum beta-lactamase resistance (ATCC BAA-196)	9/2/08	⅔ cup per gallon	10	0
Lot No. 08CGB2				10	0

MRID No. 476085-04

Lot Number	08CGB1		08CGB1 (Repetition)		08CGB2		08CGB3	
	Control	Test	Control	Test	Control	Test	Control	Test
Average CFU/ carrier	3.31×10^6	0	1.81×10^6	0	2.89×10^6	0	4.06×10^6	0
Log reduction	0	6.52046	0	6.25883	0	6.46073	0	6.60805
% reduction	0	99.99997	0	99.99994	0	99.99997	0	99.99998

VI CONCLUSIONS

1. The submitted data (MRID No. 476085-01) supports the use of the product, CPPC Ultra Bleach 2, to control *Phytophthora ramorum* chlamydospores at the 1:1000 use dilution.

2. The submitted data (MRID No. 476085-02) support the use of the product, CPPC Ultra Bleach 2, as a hard surface disinfectant with bactericidal activity against Community Associated Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) (USA 400 and 300) at the tested use dilution (⅔ cup per gallon in 100 ppm hard water) on hard, non-porous surfaces at room temperature with a contact time of 2 minutes in the presence of 5% organic soil. Controls, including resistance testing, were acceptable. Failed testing was appropriately addressed in the data package. Acceptable killing was demonstrated on all ten carriers per lot.

3. The submitted data (MRID No. 476085-03) support the use of the product, CPPC Ultra Bleach 2, as a hard surface disinfectant with bactericidal activity against *Escherichia coli* with extended spectrum beta-lactamase (ATCC BAA-196) at the tested use dilution (⅔ cup per gallon in 100 ppm hard water) on hard non-porous surfaces at

room temperature with a contact time of 2 minutes in the presence of 5% organic soil. Controls, including resistance testing, were acceptable. Acceptable killing was demonstrated on all ten carriers per lot.

4. The submitted data (MRID No. 476085-04) support the use of the product, CPPC Ultra Bleach 2, as a hard surface disinfectant with *Clostridium difficile* sporicide claims at a 1:10 use dilution (when prepared in 400 ppm hard water) at a 10 minute contact time when used on hard, non-porous surfaces. Neutralization testing showed positive growth of the microorganisms. Viability controls were positive for growth. Carrier counts were at least 1 x 10^6 spores/carrier. Sterility controls did not show growth. As a condition of registration, the registrant must request that CREM, the testing laboratory, provided the proprietary sporulation procedure to the Agency.

VII RECOMMENDATIONS

1. The proposed label claims are acceptable regarding the use of the product, CPPC Ultra Bleach 2, as a hard surface disinfectant with bactericidal activity against Community Associated Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) (USA 400 and 300) when prepared using ⅔ cup of product diluted 100 ppm hard water at a contact time of 2 minutes when used on hard non-porous surfaces at room temperature in the presence of 5% organic soil. Submitted efficacy data support these claims.

2. The proposed label claim is acceptable regarding the use of the product, CPPC Ultra Bleach 2, as a hard surface disinfectant with bactericidal activity against *Escherichia coli* with extended spectrum beta-lactamase resistance (ATCC BAA-196) when prepared using ⅔ cup of product diluted 100 ppm hard water at a contact time of 2 minutes when used on hard non-porous surfaces at room temperature in the presence of 5% organic soil. Submitted efficacy data support this claim.

3. The proposed label claim is acceptable regarding the use of the product, CPPC Ultra Bleach 2, as a disinfectant with sporicidal activity against *Clostridium difficile* (ATCC 43598) when used at the 1:10 use dilution (when prepared in 400 ppm hard water) for a contact time of 10 minutes in the presence of 5% organic soil load. Submitted efficacy data support these claims. The registrant must include the following cleaning directions on the proposed label:

Special Label Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* endospores:

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with clean cloth, mop, and/or sponge saturated with product intended for disinfection. Cleaning should included vigorous wiping and/or scrubbing, until visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms should be cleaned from right to left, with restrooms cleaned last. Do not reuse soiled cloths.

Infectious Materials Disposal: Cleaning materials used that may contain feces/wastes should be disposed of immediately in accordance with local regulations for infectious materials disposal.