UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

May 30, 2012

MEMORANDUM

Subject: Efficacy Review for CPPC Tsunami; EPA Reg. No. 67619-12; DP Barcode: 398811.

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Applicant: Clorox Professional Products Company
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P.O.Box 493
Pleasanton, CA 94566-0803

Formulation from the Label:

Active Ingredients	% by wt.
Sodium Hypochlorite	0.55 %
Other Ingredients	99.45 %
Total	100.00 %

I. BACKGROUND

The product, CPPC Tsunami (EPA Reg. No. 67619-12) is an EPA-approved disinfectant (bactericide, virucide, tuberculocide, and fungicide) on hard, non-porous surfaces in hospitals, veterinary offices, dental practices, colleges, schools, health clubs, and food service establishments. The applicant requested to amend the registration of this product to add claims or amend the exposure time of efficacy claims. Label directions indicate that the product is effective as a "one-step" disinfectant. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated February 3, 2012), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), 21 studies (MRID Nos. 487366-02 through 87366-22), Statements of No Data Confidentiality Claims for all 21 studies, and the proposed label.

II. USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: IV stands, bed pans, coated pillows and mattresses, desks, gurneys, stretchers, wheelchairs, dental surfaces, veterinary care surfaces, appliances, bathtubs, cabinets, chairs, counter tops, cribs, diaper pails, doorknobs, exterior toilet and urinal surfaces, floors, garbage cans, grocery carts, high chairs, keyboards, shower doors, showers, sinks, tables, toys, and walls. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: enamel, Formica, glass, glazed ceramic, glazed porcelain, metal (e.g., chrome, stainless steel), laminated surfaces, Marlite, plastic, porcelain enamel, synthetic marble, and vinyl. Directions on the proposed label provide the following information regarding use of the product:

> **As a Disinfectant**: Wipe surface to be disinfected. Use enough wipes for treated surface to remain visibly wet for the contact time listed below -or- on label. Let air dry. Gross filth should be removed prior to disinfecting.

Directions on the proposed label provided the following directions for use of the product against *Clostridium difficil*e spores:

> Wipe surface to be disinfected. Use enough wipes for treated surfaces to remain visibly wet for 3 minutes. Let air dry. Gross filth should be removed prior to disinfecting. Special Instruction for Cleaning Prior to Disinfection against Clostridium difficile spores. 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 product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces to minimize spreading of the spores. Restrooms are to cleaned last. Do not reuse soiled cloths.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Antimicrobial Products for Use on Hard Surfaces Using Pre-saturated or Impregnated Towelettes: Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in treating hard surfaces. The standard test methods available for hard surface disinfectants and sanitizers, if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the standard test methods. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then subculturing the slides after a specified holding time. Performance standards of the standard test methods must be met. These Agency standards are presented in EPA Pesticide Assessment Guidelines, Subdivision G, §91-2(h), Pre-saturated or impregnated towelettes; and the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes.

Sporicidal Disinfectant against *Clostridium difficile*: The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-to-use products, spray products, towelettes) that are labeled for use to treat hard, non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile*. The effectiveness of such a product must be substantiated by data derived from one of the following four test methods: Most recent version (2006) of AOAC Method 966.04: AOAC Sporicidal Activity of Disinfectants Test, Method I for *Clostridium sporogenes;* AOAC Method 2008.05: Quantitative Three Step Method (Efficacy of Liquid Sporicides Against Spores of *Bacillus subtilis* on a Hard Nonporous Surface); ASTM E 2414-05: Standard Test Method for Quantitative Sporicidal Three Step Method (TSM) to Determine Efficacy of Liquids, Liquid Sprays, and Vapor or Gases on Contaminated Carrier Surfaces; or ASTM E 2197-02: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides. Modifications to each test method will be necessary to specifically accommodate spores of *Clostridium difficile*. Because *Clostridium difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. The following toxigenic strains of *Clostridium difficile* may be used for testing: ATCC 700792, ATCC 43598, or ATCC 43599. All products must carry a precleaning step, thus no organic soil should be added to the spore inoculum. Results must show a minimum 6 log reduction of viable spores in 10 minutes or less. Control carrier counts must be greater than 10^6 spores/carrier.

Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Bacteria): The effectiveness of disinfectants for use on hard surfaces must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray or towelette products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538). To support products labeled as "general disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

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.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray or towelette products) may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least $t0^6$ conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, EPA is accepting studies with dried carrier counts that are at least $t0^4$ for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the $t0^6$ level. This interim policy will be in effect until EPA determines that the laboratories are able to achieve consistent carrier counts at the $t0^6$ level.

Disinfectants for Use as Tuberculocides (Using AOAC Tuberculocidal Activity of Disinfectants Test Method): Disinfectants may bear additional label claims of effectiveness as tuberculocides when supported by appropriate tuberculocidal effectiveness data. Certain chemical classes (i.e., glutaraldehyde and quaternary ammonium compounds) are required to undergo validation testing in addition to basic testing. Products that are formulated with other chemical groups do not require validation testing. When using the existing or modified AOAC Tuberculocidal Activity Test Methods, t0 carriers for each of 2 samples, representing 2 different product lots, must be tested against *Mycobacterium bovis* BCG (a member of the *Mycobacterium tuberculosis* species complex). Killing on all carriers/slides as demonstrated in Modified Proskauer-Beck Broth, and no growth in any of the inoculated tubes of 2 additional media (i.e., Middlebrook 7H9 Broth, Kitchener's Medium) is required.

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 or towelette 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 $t0^4$ 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.

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. BRIEF DESCRIPTION OF THE DATA

1. MRID 487366-02 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Enterobacter aerogenes* (ATCC 13048)" for CPPC Tsunami, F2010.0203, by Becky Lien. Study conducted at ATS Labs. Study completion date – December 14, 2011. Project Number A12302.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.TOW.1 (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 10.7-10.8% relative humidity. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 motions. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 21°C and 26% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average geometric mean for the test microorganism was 7.54 $\log_{10}$/carrier.

2. MRID 487366-03 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: Multidrug Resistant *Enterococcus faecium* (ATCC 51559)" for CPPC Tsunami, F2010.0203, by Becky Lien. Study conducted at ATS Labs. Study completion date – December 14, 2011. Project Number A12303.

This study was conducted against Multidrug Resistant *Enterococcus faecium* (ATCC 51559). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.TOW.2 (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 25-30°C at 60-69% relative humidity. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 motions. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 20°C and 26% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population, and antibiotic resistance. The average geometric mean for the test microorganism was 5.87 $\log_{10}$/carrier.

Note: Antimicrobial Susceptibility Testing was conducted on a representative culture using MIC method, against several antibiotics, and found to be resistant to Ampicillin, Penicillin, Vancomycin, and Gentamicin (Tobramycin and Amikacin). See "Attachment I" on page 16 of the laboratory report.

3. MRID 487366-04 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Klebsiella pneumoniae* – New Delhi Metallo – Beta Lactamase-1 (CDC 1000527)" for CPPC Tsunami, F2010.0203, by Becky Lien. Study conducted at ATS Labs. Study completion date – December 19, 2011. Project Number A12304.

This study was conducted against *Klebsiella pneumoniae* – New Delhi Metallo – Beta Lactamase-1 (CDC 1000527). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.TOW.3 (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 motions. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 21°C and 34% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population, antibiotic resistance. The average geometric mean for the test microorganism was 6.53 $\log_{10}$/carrier.

Note: Antimicrobial Susceptibility Testing was conducted on a representative culture using MIC method, against several β-lactam antibiotics, and found to be resistant to all of them. See "Attachment I" on page 17 of the laboratory report.

4. MRID 487366-05 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Escherichia coli* – New Delhi Metallo – Beta Lactamase-1 (CDC 1001728)" for CPPC Tsunami, F2010.0203, by Becky Lien. Study conducted at ATS Labs. Study completion date – December 14, 2011. Project Number A12305.

This study was conducted against *Escherichia coli* – New Delhi Metallo – Beta Lactamase-1 (CDC 1000527). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.TOW.4 (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 motions. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 21°C and 34% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier

population and antibiotic resistance. The average geometric mean for the test microorganism was 6.67 log_{10}/carrier.

Note: Antimicrobial Susceptibility Testing was conducted on a representative culture using MIC method, against several β-lactam antibiotics, and found to be resistant to all of them. See "Attachment I" on page 17 of the laboratory report.

5. MRID 487366-06 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: Linezolid Resistant *Staphylococcus aureus* (NRS 119)" for CPPC Tsunami, F2010.0203, by Becky Lien. Study conducted at ATS Labs. Study completion date – January 6, 2012. Project Number A12306.

This study was conducted against Linezolid Resistant *Staphylococcus aureus* (LRSA)(NRS 119). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.TOW.5 (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 31 minutes at 35-37°C at 40-42% relative humidity. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 motions. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 20°C and 22% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population and antibiotic resistance. The average geometric mean for the test microorganism was 6.30 log_{10}/carrier.

Note: Antibiotic resistance of Linezolid Resistant *Staphylococcus aureus* (LRSA)(NRS 119) was verified on a representative culture. An individual Mueller Hinton agar plate was streaked with the prepared culture. A control agar was prepared using *Staphylococcus aureus* (ATCC 25923) as a control organism. A linezolid disk was added to the center of each plate. The plates were incubated and, following incubation, the zones of inhibition were measured. The measurement confirmed antibiotic resistance of Linezolid Resistant *Staphylococcus aureus* (LRSA)(NRS 119) to linezolid. See page 17 of the laboratory report.

6. MRID 487366-07 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705)" for CPPC Tsunami, F2010.0203, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – January 3, 2012. Project Number A12327.

This study was conducted against Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.TOW.6 (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40-41% relative humidity. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 motions. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers

were allowed to remain wet for 30 seconds at 22.8°C and 18.2% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population and antibiotic resistance. The average geometric mean for the test microorganism was 6.83 $\log_{10}$/carrier.

Note: Antibiotic resistance of Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705) and Carbapenemase detection on Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705) were verified on a representative culture. A 10 µg Meropenem (an antibiotic of Carbapenem class) placed in the center of a Mueller Hinton agar plate inoculated with *Escherichia coli* (ATCC 25922) was streaked with prepared culture of a positive control (*Klebsiella pneumoniae* ATCC BAA-1705) and negative control (*Klebsiella pneumoniae* ATCC BAA-1706) as a control organism. The plate was incubated and, following incubation, examined for the presence of the cloverleaf indentation. The examination confirmed production of carbapenemase then antibiotic resistance of Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705) to Carbapenem (Meropenem). See page 17 of the laboratory report.

7. MRID 487366-08 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Enterobacter cloacae* (ATCC 13047)" for CPPC Tsunami, F2010.0203, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – January 5, 2012. Project Number A12328.

This study was conducted against *Enterobacter cloacae* (ATCC 13047). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.TOW.7 (copy provided) (modified for towelette products) as described in the AOAC Official Methods of Analysis, 2009. The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 motions. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 21°C and 19% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average geometric mean for the test microorganism was 7.56 $\log_{10}$/carrier.

8. MRID 487366-09 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Proteus mirabilis* (ATCC 9240)" for CPPC Tsunami, F2010.0203, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – January 5, 2012. Project Number A12329.

This study was conducted against *Proteus mirabilis* (ATCC 9240). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.TOW.8 (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old

suspension of test organism. The carriers were dried for 30 minutes at 25-30°C at 60% relative humidity. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 motions. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 21°C and 19% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average geometric mean for the test microorganism was 7.25 $\log_{10}$/carrier.

9. MRID 487366-10 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Serratia marcescens* (ATCC 14756)" for CPPC Tsunami, F2010.0203, by Christine Chan. Study conducted at ATS Labs. Study completion date – January 4, 2012. Project Number A12330.

This study was conducted against *Serratia marcescens* (ATCC 14756). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.TOW.9 (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 motions. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 22.9°C and 17.5% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average geometric mean for the test microorganism was 7.41 $\log_{10}$/carrier.

10. MRID 487366-11 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Campylobacter jejuni* (ATCC 29428)" for CPPC Tsunami, F2010.0203, by Christine Chan. Study conducted at ATS Labs. Study completion date – January 10, 2012. Project Number A12456.

This study was conducted against *Campylobacter jejuni* (ATCC 29428). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18120811.TOW (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 25-30°C at 65% relative humidity. Each inoculated carrier was treated with two passes, where one pass equals a back and forth motion for a total of 4 passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 21°C and 17% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 3 days at 35-37°C under microaerophilic conditions. Following incubation, the subcultures were examined for the presence or absence of visible growth.

Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average geometric mean for the test microorganism was 5.75 $\log_{10}$/carrier.

Note: The protocol amendment reported was reviewed.

> **11. MRID 487366-12 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: Extended Spectrum Beta-Lactamase producing *Klebsiella pneumoniae* (CDC 700603)" for CPPC Tsunami, F2010.0203, by Christine Chan. Study conducted at ATS Labs. Study completion date – January 4, 2012. Project Number A12333.**

This study was conducted against Extended Spectrum Beta-Lactamase producing *Klebsiella pneumoniae* (CDC 700603). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.TOW.12 (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 motions. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 22.9°C and 17.5% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population, and antibiotic resistance. The average geometric mean for the test microorganism was 6.61 $\log_{10}$/carrier.

Note: Antibiotic resistance of Extended Spectrum Beta-Lactamase producing *Klebsiella pneumoniae* (CDC 700603) was verified on a representative culture. An individual Mueller Hinton agar plate was streaked with the prepared culture. Negative control and positive control agars were prepared using respectively *Escherichia coli* (ATCC 35218) and *Klebsiella pneumoniae* (ATCC 700603). Two Etest strips, one containing Cefotaxime (CT) and Cefotaxime+Clavulanic acid (CTL) and the other Ceftazidime (TZ) and Ceftazidime+Clavulanic acid (TZL) were placed on each plate. The plates were incubated and, following incubation, the Minimum Inhibitory Concentration (MIC) was read. The measurement confirmed production of Extended Spectrum Beta-Lactamase by Extended Spectrum Beta-Lactamase producing *Klebsiella pneumoniae* (CDC 700603). See pages 17 and 18 of the laboratory report.

> **12. MRID 487366-13 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: Vancomycin Resistant *Staphylococcus aureus* - VRSA (NRSA VRS1)" for CPPC Tsunami, F2010.0203, by Anne Stemper. Study conducted at ATS Labs. Study completion date – December 19, 2011. Project Number A12309.**

This study was conducted against Vancomycin Resistant *Staphylococcus aureus - VRSA* (NRSA VRS1). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.TOW.13 (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 2 day old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each inoculated carrier was treated with two

passes, where one pass equals a back and forth motion for a total of 4 passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 23.5°C and 22.2% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population, and antibiotic resistance. The average geometric mean for the test microorganism was 6.13 $\log_{10}$/carrier.

Note: Antibiotic resistance of Vancomycin Resistant *Staphylococcus aureus* (NRSA VRS1) was verified on a representative culture. An individual Mueller Hinton agar plate was streaked with the prepared culture. A control agar was prepared using *Staphylococcus aureus* (ATCC 29213) as a control organism. A Vancomycin Etest strip was placed on each plate. The plates were incubated and, following incubation, the Minimum Inhibitory Concentration (MIC) was read. The measurement confirmed antibiotic resistance of Vancomycin Resistant *Staphylococcus aureus* (NRSA VRS1) to Vancomycin. See page 17 of the laboratory report.

13. **MRID 487366-14 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: Vancomycin Intermediate Resistant *Staphylococcus aureus* - VISA (HIP 5836)"** for CPPC Tsunami, F2010.0203, by **Anne Stemper. Study conducted at ATS Labs. Study completion date – January 4, 2012. Project Number A12310.**

This study was conducted against Vancomycin Intermediate Resistant *Staphylococcus aureus* - VISA (HIP 5836). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.TOW.14 (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 2 day old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 41% relative humidity. Each inoculated carrier was treated with two passes, where one pass equals a back and forth motion for a total of 4 passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 22.9°C and 22.6% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population, and antibiotic resistance. The average geometric mean for the test microorganism was 5.61 $\log_{10}$/carrier.

Note: Antibiotic resistance of Vancomycin Intermediate Resistant *Staphylococcus aureus* (HIP 5836) was verified on a representative culture. An individual Mueller Hinton agar plate was streaked with the prepared culture. A control agar was prepared using *Staphylococcus aureus* (ATCC 29213) as a control organism. A Vancomycin Etest strip was placed on each plate. The plates were incubated and, following incubation, the Minimum Inhibitory Concentration (MIC) was read. The measurement confirmed intermediate antibiotic resistance of Vancomycin Intermediate Resistant *Staphylococcus aureus* (HIP 5836) to Vancomycin. See page 17 of the laboratory report.

14. **MRID 487366-15 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Bordetella pertussis* (ATCC 12743)"** for CPPC Tsunami, F2010.0203, by

Nicole Albert. Study conducted at ATS Labs. Study completion date – January 4, 2012. Project Number A12323.

This study was conducted against *Bordetella pertussis* (ATCC 12743). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18111411.TOW (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 6 day old suspension of test organism. The carriers were dried for 30 minutes at 25-30°C at 65% relative humidity. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 motions. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 22.9°C and 11.9% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were filtered through a 0.45 micron filter and incubated for 4 days at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average geometric mean for the test microorganism was 6.49 $\log_{10}$/carrier.

Note: The protocol deviation reported was reviewed.

15. MRID 487366-16 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Trichophyton mentagrophytes* (ATCC 9533)" for CPPC Tsunami, F2010.0203, by Anne Stemper. Study conducted at ATS Labs. Study completion date – January 5, 2012. Project Number A12322.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.FTOW.3 (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the conidial suspension to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 10 day old suspension of test organism. The carriers were dried for 39 minutes at 35-37°C at 51% relative humidity. Each inoculated carrier was treated with two passes, where one pass equals a back and forth motion for a total of 4 passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 3 minutes at 22.9°C and 18% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Sabouraud Dextrose Broth containing 0.1% sodium thiosulfate to neutralize. The carriers were transferred from the primary subcultures into individual secondary subcultures containing 40 mL quantities of Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 at ≥30 minutes following the first transfer. All subcultures were incubated for 10 days at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average geometric mean for the test microorganism was 5.65 $\log_{10}$/carrier.

16. MRID 487366-17 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Candida albicans* (ATCC 10231)" for CPPC Tsunami, F2010.0203, by Anne Stemper. Study conducted at ATS Labs. Study completion date – January 4, 2012. Project Number A12320.

This study was conducted against *Candida albicans* (ATCC 10231). Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested using ATS Labs protocol # CX18110711.FTOW.1 (copy provided). The product was received ready-to-use as pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 microliters of a 2 day old culture of test organism. The carriers were dried for 30 minutes at 25-30°C at 60-63% relative humidity. Each inoculated carrier was treated with two passes, where one pass equals a back and forth motion for a total of 4 passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 3 minutes at 22.9°C and 18% relative humidity. Following exposure, individual carriers were transferred to 40 mL of Sabouraud Dextrose Broth containing 0.1% sodium thiosulfate to neutralize. The carriers were transferred from the primary subcultures into individual secondary subcultures containing 40 mL quantities of Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 at ≥30 minutes following the first transfer. All subcultures were incubated for 3 days at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average geometric mean for the test microorganism was 5.55 $\log_{10}$/carrier.

17. MRID 487366-18 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: Canine Parvovirus, Strain Cornell-780916-80 (ATCC VR-2017)" for CPPC Tsunami, F2010.0203, by Shanen Conway. Study conducted at ATS Labs. Study completion date – December 19, 2011. Project Number A12295.

This study was conducted against Canine Parvovirus (Strain Cornell-780916-80 (ATCC VR-2017)) using A-72 cells (canine tumor cells; ATCC CRL-1542) as the host system. Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested according to ATS Labs Protocol No. CX18110711.CPV (copy provided). The product was received ready-to-use as pre-saturated towelette. The stock virus culture contained 5% fetal bovine serum as the 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 for 20 minutes at 20.0°C at 50% relative humidity. One replicate per product lot was tested. For each lot of product, separate dried virus films were wiped with a saturated towelette from each batch of test substance. Each carrier was divided into two sections for wiping. Each section was wiped using two passes, where one pass equals a back and forth motion, for a total of four motions. A new unused area of the folded towelette was exposed for each section. The sections were treated in such a way that overlapping was minimal. The treated dish was held covered for 3 minutes at 20.0°C. Following exposure, a 2mL aliquot of test medium was added and the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. A-72 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

18. MRID 487366-19 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: Feline Panleukopenia virus, Strain

Philips-Roxane (ATCC VR-648)" for CPPC Tsunami, F2010.0203, by Kelleen Gutzman. Study conducted at ATS Labs. Study completion date – December 14, 2011. Project Number A12294.

This study was conducted against Feline Panleukopenia virus (Strain Philips-Roxane (ATCC VR-648)) using CRFK cells (feline kidney cells; ATCC CCL-94) as the host system. Two lots (Lot Nos. 11CMK1 and 11CMK2) of the product, CPPC Tsunami, were tested according to ATS Labs Protocol No. CX18110711.FPLV (copy provided). The product was received ready-to-use as pre-saturated towelette. The stock virus culture was adjusted to contain 5% fetal bovine serum as the 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 for 20 minutes at 20.0°C at 50% relative humidity. One replicate per product lot was tested. For each lot of product, separate dried virus films were wiped with a saturated towelette from each batch of test substance. Each carrier was divided into two sections for wiping. Each section was wiped using two passes, where one pass equals a back and forth motion, for a total of four motions. A new unused area of the folded towelette was exposed for each section. The sections were treated in such a way that overlapping was minimal. The treated dish was held covered for 3 minutes at 20.0°C. Following exposure, a 2mL aliquot of test medium was added and the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 10% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 14 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: The protocol deviation reported was reviewed.

19. MRID No. 487366-20 "AOAC Tuberculocidal Activity of Disinfectant Towelette Products," Test Organism: *Mycobacterium bovis* - BCG, for CPPC Tsunami, F2010.0203, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – September 2, 2011. Project Number A11331.

This study was conducted against *Mycobacterium bovis* - BCG (obtained from Organon Teknika Corporation, Durham, NC). Two lots (Lot Nos. 11CGW3 and 11CGW4) of the product, CPPC Tsunami, were tested using ATS Labs Protocol No. CX18041211.TB.2 (copy provided). The product was received ready-to-use as a pre-saturated towelette. Fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. Ten (10) glass slide carriers (3" x 1") per product lot were inoculated with 10.0 µL of a 23 day old suspension of test organism. Inoculum was uniformly spread over a 1" x 1" area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 40% humidity. Each inoculated carrier was treated with two passes, where one pass equals a back and forth motion for a total of 4 motions. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The treated surface was allowed to remain exposed to the product for 3 minutes at 22.5°C at 23.4% relative humidity. Following exposure, the carriers were transferred to individual tubes of 40 mL of MB Neutralizer. The carriers were transferred to individual tubes containing 40 mL of Modified Proskauer-Beck Medium. From each tube of neutralizer, 2.0 mL were cultured to tubes containing 20 mL of Middlebrook 7H9 Broth and 2.0 mL were cultured to tubes containing 20 mL of Kirchner's Medium. All tubes used for secondary transfers were incubated for 90 days at 35-

37°C under aerobic conditions. The tubes were visually examined after 30, 61, and 90 days of incubation. Controls included those for initial suspension population, carrier population, purity, sterility, viability, and neutralization confirmation. The average carrier count for the test microorganism was 3.9 x 10^5 CFU /carrier.

20. MRID No. 487366-21, "Standard Quantitative Disk Carrier Test Method," Test Organism: *Clostridium difficile* – spore form (ATCC 43598)," for CPPC Tsunami, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – January 31, 2012. Project Number A12374.

The study was conducted against *Clostridium difficile* spores (ATCC 43598). Three lots (Lot Nos. 11CMK1, 11CMK2, and 11SUK5 (≥60 days old)) of the product, CPPC Tsunami, were tested using ASTM E2197-02, Standard Quantitative Disk Carrier Test Method for Determining the Bactericidal, Virucidal, Fungicidal, Mycobactericidal and Sporicidal Activities of Liquid Chemical Germicides, as specified by the US EPA in Guidance for the Efficacy Evaluation of Products with Sporicidal Claims Against *Clostridium difficile* (February 5, 2009). The liquid used in testing was expressed from the towelettes prior to use. Two towelettes per lot of test substance were added to a sterile syringe for extraction of the liquid test product. Sterilized stainless steel disks were inoculated with 0.01 ml spore suspension demonstrating 93% purity. The Petri plates containing the inoculated carriers were transferred to desiccators, and dried under vacuum for approximately 2.5 hours at ambient conditions. Post-drying, each carrier was transferred to a sterile vial. A 0.05ml aliquot of test formulation or control solution was transferred onto the surface of the inoculated carrier. Each carrier was exposed to the solution for 3 minutes at 20°C and 17% relative humidity. Post-exposure, 10 ml neutralizing solution (Letheen Broth with 0.1% sodium thiosulfate) was added to each vial. To elute surviving spores, the carriers were scraped with a 4mm sterile loop and vortex mixed for approximately 45-60 seconds. The procedure was repeated in sequential fashion until 10 contaminated carriers had been treated with each lot of the test formulation, and 6 inoculated carriers had been treated with the control solution. For the control carriers, serial 10-fold dilutions of the neutralizing solution from each carrier were prepared in saline. Aliquots of the 10^{-3}, 10^{-4}, and 10^{-5} dilutions were each vacuum-filtered using 0.2 micron pore-size membranes. For test carriers, the entire fluid volume of each 10^0 dilution vial was vacuum-filtered using separate sterile analytical filter units with 0.2 micron pore-size membranes. Each vial was rinsed three times with 15 ml 0.85% saline, and the rinsates were filtered. Test and control membrane filters were transferred to the surface of CCFA-HT agar. The plates were incubated anaerobically at 35-37°C for 48±4 hours. Controls included those for HCl resistance, purity, sterility, neutralization effectiveness confirmation, initial suspension population control, and spore purity control.

21. MRID No. 487366-22, "Towelette Wetness Test," for CPPC Tsunami, by Michael Way. Study Conducted at Antimicrobial Test Laboratories. Study Completion Date-January 31, 2012. Study Identification Number-GLP1101.

The purpose of this study was to determine the residual wetness of test carriers following treatment and a 3 minute contact time. Three lots (Lot Nos. 11CMK1, 11CMK2, and 11SUK5 (≥60 days old)) of the product, CPPC Tsunami, were tested using the study design approved by the EPA for Caltech Industries, Inc. (now owned by the Clorox Company) for observing and measuring the surface wetness imparted by using a disinfectant towelette (protocol attached). The test carriers were composed of new Formica (Black Matte Finish, e.g. style 909-58) cut to a 12 inch by 12 inch size. The test carriers were wiped with a damp cloth and allowed to air dry prior to initiation of the study in order to remove dust. The back of each test carrier was labeled with a unique identifier (e.g. "A," "B," "C,") by permanent marker. The

exposure portion of the test was controlled by a calibrated timer. One towelette was used to wipe each test carrier (one wipe treated one 12" x 12" carrier). Three (3) towelettes were evaluated per lot. To begin the study, laboratory staff initiated the video recording of the study. The first test carrier was weighed prior to treatment using a calibrated laboratory balance with an accuracy of 0.01 g. Ten (10) towelettes were removed from the towelette package to demonstrate wetness throughout the towelette container. The next towelette was used for the initial test carrier. For the second carrier, 10 more towelettes were removed and the next towelette was used. For the third carrier, another 10 towelettes were removed and then the next towelette was used for that test. The towelette container was securely closed between removals of each set of 11 test towelettes. The towelette was unfolded. The towelette was folded in half twice, once along the length and once along the width. The towelette was placed on the top left corner of the test carrier. The test carrier was wiped in an up and down motion, each stroke slightly overlapping the last; until the entire test carrier was completely covered (5-7 total strokes with the wipe were used on each 12" x 12" carrier). After the entire test surface area was treated, the timer was started. The carrier was placed on the balance and the initial wet weight of the test carrier was recorded. The test carrier was allowed to sit undisturbed for the 3 minute contact time. Upon completion of the contact time, the final wet weight of the test carrier was recorded. Immediately after weighing, a single sheet of unfolded cigarette paper was wiped across the test surface to assist in visualization of wetness for the laboratory technician and video camera due to the clear colorless nature of the test substance. Visual wetness of the cigarette paper was defined as wetness. The paper wetness was observed and recorded.

Note: The editorial protocol amendments were reviewed.

V. RESULTS

Hard Surface Bactericidal & Fungicidal Disinfection Results:

MRID Number	Organism	No. Carriers Exhibiting Growth/Total Carriers		Carrier Population (Log_{10}CFU/Carrier)
		Lot # 11CMK1	Lot # 11CMK2	
487366-02	*Enterobacter aerogenes* (ATCC 13048)	0/10	0/10	7.54
487366-03	*Enterococcus faecium* (ATCC 51559) (Multi-drug resistant)	0/10	0/10	5.87
487366-04	*Klebsiella pneumoniae* New Delhi Metallo-Beta Lactamase-1 (CDC 1000527)	0/10	0/10	6.53
487366-05	*Escherichia coli* New Delhi Metallo-Beta Lactamase-1 (NDM-1 E. coli) (CDC 1001728)	0/10	0/10	6.67
487366-06	Linezolid resistant *Staphylococcus aureus* (LRSA) (NRS 119)	0/10	0/10	6.30
487366-07	Carbapenem resistant *Klebsiella pneumoniae*	0/10	0/10	6.83

	(ATCC BAA-1705)			
487366-08	*Enterobacter cloacae* (ATCC 13047)	0/10	0/10	7.56
487366-09	*Proteus mirabilis* (ATCC 9240)	0/10	0/10	7.25
487366-10	*Serratia marcescens (ATCC 14756)*	0/10	0/10	7.41
487366-11	*Campylobacter jejuni (ATCC 29428)*	0/10	0/10	5.75
487366-12	Extended Spectrum beta-lactamase (ESBL) producing *Klebsiella pneumoniae* (CDC 700603)	0/10	0/10	6.61
487366-13	Vancomycin resistant *Staphylococcus aureus* (VRSA) (NARSA VRS1)	0/10	0/10	6.13
487366-14	Vancomycin intermediate resistant *Staphylococcus aureus* (VISA) (HIP 5836)	0/10	0/10	5.61
487366-15	*Bordetella pertussis* (ATCC 12743)	0/10	0/10	6.49
487366-16	Trichophyton mentagrophytes (ATCC 9533)	0/10, 0/10	0/10, 0/10	5.65
487366-17	*Candida albicans* (ATCC 10231)	0/10, 0/10	0/10, 0/10	5.55

Hard Surface Virucidal Disinfection Results:

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1mL)
		Description	Lot # 11CMK1	Lot # 11CMK2	
487366-18	Canine Parvovirus (ATCC VR-2017)	10^{-1} to 10^{-8} dilutions	Complete Inactivation	Complete Inactivation	$10^{4.75}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		TCD_{50}/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.25	≥4.25	
487366-19	Feline Panleukopenia Virus (ATCC VR-648)	10^{-1} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	$10^{4.50}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		TCD_{50}/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.00	≥4.00	

Hard Surface Tuberculocidal Disinfection Results:

MRID Number	Organism	Media	No. Exhibiting Growth @ 90 days/Total No. Tested		
			Lot # 11CMK1	Lot # 11CMK2	Lot # 11SUK5
487366-20	Mycobacterium bovis BCG Carrier Population: 3.9×10^5 CFU/carrier	Modified Proskauer-Beck Medium	0/10	0/10	0/10
		Middlebrook 7H9 Broth	0/10	0/10	0/10
		Kirchner's Medium	0/10	0/10	0/10

Hard Surface *C. difficile* Sporicidal Disinfection Results: MRID # 487366-21

Test Results

Lot No.	Carrier Number	Mean CFU/carrier	Mean Log_{10} CFU/carrier	Mean Log_{10} Density	Mean Log_{10} Reduction
11CMK1	1-10	<1	<0.0	<0.0	>6.80
11CMK2	1-10	<1	<0.0	<0.0	>6.80
11SUK5	1-10	2.00×10^0	0.3	0.3	6.50

Untreated Dried Carrier Control Results:

Untreated Carrier No.	CFU/carrier	Log_{10} Carrier	Mean Log_{10} Density
1	3.8×10^6	6.58	6.80
2	5.1×10^6	6.71	
3	1.27×10^7	7.10	

HCl Resistance Control Results:

Test Organism	Mean Log_{10} Reduction		
	5 minutes	10 minutes	20 minutes
C. difficile spores	1.05	1.49 (PASS)	2.53

Visual & Gravimetric Wetness Testing: MRID # 487366-22

Lot No.	Carrier Number	Visual Wetness Confirmed
11CMK1	1	Yes
	2	Yes
	3	Yes
11CMK2	1	Yes
	2	Yes
	3	Yes
11SUK5 (≥60 days old)	1	Yes
	2	Yes
	3	Yes

Lot No.	Carrier Number	Initial Carrier Dry Weight	Initial Carrier Wet Weight	Final Carrier Weight	Remaining Test Substance	Wetness Confirmation
11CMK1	1	80.73	81.40	81.25	0.52	Yes
	2	82.19	82.54	82.33	0.14	Yes
	3	81.85	82.38	82.14	0.29	Yes
11CMK2	1	80.19	81.11	80.84	0.65	Yes
	2	83.79	84.77	84.51	0.72	Yes
	3	83.31	83.98	83.71	0.40	Yes
11SUK5 (≥60 days old)	1	84.43	84.83	84.73	0.30	Yes
	2	84.64	85.23	84.96	0.32	Yes
	3	82.79	83.34	83.12	0.33	Yes

VI. CONCLUSIONS

1. The submitted efficacy data support the use of the product, CPPC Tsunami, as a disinfectant with bactericidal activity against the following microorganisms on hard, nonporous surfaces in the presence of a 5% organic soil load for a 30 seconds contact time:

Enterobacter aerogenes	MRID # 487366-02
Multi-drug Resistant *Enterococcus faecium*	MRID # 487366-03
Klebsiella pneumoniae New Delhi Metallo-Beta Lactamase-1	MRID # 487366-04
Escherichia coli New Delhi Metallo-Beta Lactamase-1	MRID # 487366-05
Linezolid resistant *Staphylococcus aureus* (LRSA)	MRID # 487366-06
Carbapenem resistant *Klebsiella pneumoniae* (CRP)	MRID # 487366-07
Enterobacter cloacae	MRID # 487366-08
Proteus mirabilis	MRID # 487366-09
Serratia marcescens	MRID # 487366-10
Campylobacter jejuni	MRID # 487366-11
Extended Spectrum Beta Lactamase producing *Klebsiella pneumoniae*	MRID # 487366-12
Vancomycin resistant *Staphylococcus aureus* (VRSA)	MRID # 487366-13
Vancomycin intermediate resistant *Staphylococcus aureus* (VISA)	MRID # 487366-14
Bordetella pertussis	MRID # 487366-15

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data support the use of the product, CPPC Tsunami, as a disinfectant with fungicidal activity against the fungal strains listed below in the presence of a 5% organic soil load for a 3-minute contact time.

Trichophyton mentagrophytes	MRID # 487366-16
Candida albicans	MRID # 487366-17

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganism. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

3. The submitted efficacy data **support** the use of the product, CPPC Tsunami, as a disinfectant with virucidal activity against the viral strains listed below on hard, non-porous surfaces in the presence of a 5% organic soil load for a 3-minute contact time:

Canine Parvovirus	MRID # 487366-18
Feline Panleukopenia Virus	MRID # 487366-19

Recoverable virus titers of at least 10^4 were achieved. No cytotoxicity was observed. Complete inactivation (no growth) was indicated in all dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

4. The submitted efficacy data (MRID # 487366-20) **support** the use of the product, CPPC Tsunami, as a disinfectant with tuberculocidal activity against *Mycobacterium bovis* BCG on hard, non-porous surfaces in the presence of a 5% organic soil load for a 3-minute contact time. No growth was observed in the subcultures. Neutralization confirmation testing showed positive growth of the microorganism in all test media. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

5. The submitted efficacy data (MRID # 487366-21) **supports** the use of the product, CPPC Tsunami, as a disinfectant with sporicidal activity against *Clostridium difficile*—spore form on pre-cleaned hard, non-porous surfaces for a contact time of 3 minutes. Neutralization confirmation testing showed positive growth of the microorganism. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. *Clostridium difficile* spores showed acid resistance to acid for ≥10 minutes. The wetness determination (as described in MRID No. 480900-01) demonstrated weight and visual wetness endpoints for confirming wetness consistent with the proposed contact time. The submitted efficacy data is acceptable.

VII. LABEL

1. The proposed label claims are acceptable regarding the use of the product, CPPC Tsunami, as a disinfectant with bactericidal activity for use on hard, non-porous surfaces against the following microorganisms when used undiluted in the presence of 5% organic soil, at room temperature, for a 30 seconds contact time. These claims are supported by the applicant's data:

Enterobacter aerogenes
Multi-drug Resistant *Enterococcus faecium* (**must qualify multidrug and list drugs:** Ampicillin, Penicillin, Vancomycin, and Gentamicin)
Klebsiella pneumoniae New Delhi Metallo-Beta Lactamase-1 (NDM-1 *K. pneumoniae)*
Escherichia coli New Delhi Metallo-Beta Lactamase-1 (NDM-1 E. coli)
Linezolid resistant *Staphylococcus aureus* (LRSA)
Carbapenem resistant *Klebsiella pneumoniae*
Enterobacter cloacae
Proteus mirabilis

Serratia marcescens
Campylobacter jejuni
Extended Spectrum Beta Lactamase producing *Klebsiella pneumoniae*
Vancomycin resistant *Staphylococcus aureus* (VRSA)
Vancomycin intermediate resistant *Staphylococcus aureus* (VISA)
Bordetella pertussis

2. The proposed label claims are acceptable regarding the use of the product, CPPC Tsunami, as a disinfectant with fungicidal activity on hard, non-porous surfaces when used undiluted in the presence of 5% organic soil, at room temperature, for a contact time of 3 minutes. These claims are supported by the applicant's data:

Trichophyton mentagrophytes
Candida albicans

3. The proposed label claims are acceptable regarding the use of the product, CPPC Tsunami, as a disinfectant with virucidal activity on hard, non-porous surfaces when used undiluted in the presence of 5% organic soil, at room temperature, for a contact time of 3 minutes. These claims are supported by the applicant's data:

Canine Parvovirus
Feline Panleukopenia Virus

4. The proposed label claims are acceptable regarding the use of the product, CPPC Tsunami, as an effective disinfectant against *Mycobacterium bovis* on hard, non-porous surfaces in the presence of a 5% organic soil load for a 3-minute contact time. This claim is acceptable as it is supported by the submitted data.

5. The proposed label claims are acceptable regarding the use of the product, CPPC Tsunami, as a sporicide wipe against *Clostridium difficile* on pre-cleaned hard, non-porous surfaces for a 3-minute contact time. This claim is acceptable as it is supported by the submitted data.

6. On the proposed label, under the heading Blood-borne Pathogens, include Hepatitis C [(as bovine diarrhea virus)].