UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

Revised Review, June 9, 2011
(Original Review, May 5, 2011)

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 67619-12, CPPC Tsunami;

From: Tajah L. Blackburn, Ph.D., Microbiologist
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Antimicrobials Division (7510P)

To: Wanda Henson PM32
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Applicant: The Clorox Company
PO Box 493
Pleasanton, CA 94566-0803

Formulation from the Label:

Active Ingredient(s)	% by wt.
Sodium Hypochlorite	0.55%
Other Ingredients	99.45%
Total	100.00%

I BACKGROUND

The towelette product, CPPC Tsunami (EPA Reg. No. 67619-12), is an EPA-approved disinfectant (bactericide, fungicide, virucide), mildewcide, and deodorizer for use on hard, non-porous surfaces in household, commercial, institutional, industrial, food service, animal care, and hospital or medical environments. The applicant requested to amend the registration of this product to add new claims for effectiveness as a disinfectant against *Clostridium difficile* – spore form. In response to the Agency's review (May 5, 2011), the registrant provided an email rebuttal on May 16, 2011. The current review addresses the comments provided in the rebuttal, and outlines the status of the current amendment. To address the Agency's Recommendation, the registrant's email stated that "[Clorox] made all the required label changes in this section...the C. diff directions for use [the registrant] added to this label are consistent with the directions for use for CPPC Ultra Bleach 2, EPA Reg. No. 67619-8." A revised label was not provided with the rebuttal. As a result, the current review will not include a review of the label. Studies were conducted at BioScience Laboratories, Inc., located at 300 N. Willson Avenue, in Bozeman, MT 59715.

II USE DIRECTIONS (From previous submission)

The product is designed for disinfecting hard, non-porous surfaces. The product may be used to treat hard, non-porous surfaces, including: air vent exteriors, appliances, automatic feeders, bathroom fixtures, bathtubs, bed frames, bed pans, bed railings, booster chairs, cabinet handles, cabinets, cages, carts, ceilings, cellular phones, chairs, closet handles, computer keyboards and monitors, counters, cribs, desk tops, diaper changing stations, diaper pails, dictating equipment, dish racks, doorknobs, drain boards, drawers, examination tables, faucets, feed racks, floors, food cases and trays, fountains, garbage cans, hampers, hand railings, headsets, high chairs, hospital equipment (e.g., gurneys, IV stands, stretchers, wheelchairs), lamps, mattress covers, outdoor furniture (excluding wood frames and upholstery), pens, pipes, playpens, shelves, shower fixtures, shower stalls, sinks, sneeze guards, stalls, tables, telecommunication equipment, telephones, television remote controls, towel dispensers, toys, troughs, urinal surfaces, vanity tops, veterinary equipment, walls, wash basins, and watering appliances. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: baked enamel, chrome, Formica, glass, glazed ceramic, glazed porcelain, laminated surfaces, linoleum, Marlite, plastic, porcelain enamel, stainless steel, synthetic marble, and vinyl. Directions on the proposed label provide the following information regarding preparation and use of the product as a disinfectant against *Clostridium difficile* spores: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection. 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 be cleaned last. Do not reuse soiled cloths. Wipe surface to be disinfected. Use enough wipes for treated surface to remain visibly wet for 5 minutes. Let air dry. Gross filth should be removed prior to disinfecting.

III AGENCY'S REVIEW COMMENTS AND REGISTRANT'S REBUTTAL

Agency's Conclusion 1. The submitted efficacy data (MRID 483771-01 through 483771-03) do not support the use of the expressed liquid of the towelette product, CPPC Tsunami, F2010.0203, as a disinfectant against *Clostridium difficile* on pre-cleaned, hard, non-porous surfaces for a 4.5-minute contact time. The registrant needs to provide information pertaining to (a) the number of towelettes used to obtain the expressed liquid; (b) define retained sample as stated in MRID No. 483771-01 (Lot# 10CGW2E); (c) provide clarity regarding the dilution of the expressed liquid as stated in the MRID No. 483771-01; (d) explain the change in filter pore size from 0.22 µm to 0.45 µm; and (e) identify the aged lot. At least a 6-log reduction in viable spores was observed. Neutralizer efficacy verification testing showed growth of the "test" population not more than 0.25 $\log_{10}$ less than the average control population. Purity controls were reported as pure. The sterility controls did not show growth. Acid resistance testing met the acceptance criterion of growth following a 2-minute exposure.

Registrant's Response to (a). The number of towelettes used to obtain the expressed liquid:

- Lot 10CGW2L, three towelettes were centrifuged to obtain expressed liquid;
- Lot 10CGW2E, two towelettes were centrifuged to obtain expressed liquid;
- Lot 10CGW7, two towelettes were centrifuged to obtain expressed liquid;
- Lot 10CGW8, two towelettes were centrifuged to obtain expressed liquid

Registrant's Response to (b). In this study, the "retained sample" is a replicate canister of the disinfectant wipe product, retained by the Study Sponsor. It is representative of Lot # 10CWG2, which is the aged lot (> 60 days old). This "retained sample" was used to create "Test Solution #2 (Lot # 10CGW2E)" as indicated in MRID No. 483771-01.

Registrant's Response to (c). GLP initial characterization of aged Lot # 10CGW2, sample canister #10CGW2-1 gave titration results of 0.5567% NaOCl (higher than the lower certified limit (LCL on the Confidential Statement of Formula (CSF)). Therefore the sample was diluted by Clorox as follows:

1. Remaining wipes from sample canister #10CGW2-1 were centrifuged at 3000 rpm for 15 minutes.
2. The resulting lotion from each wipe was combined in a Nalgene bottle and dilutes with an appropriate amount of deionized water from the CTC (Clorox Technical Center) pilot plant to achieve sodium hypochlorite (NaOCl) concentration of 0.5% (the LCL) using the calculation below:
3. The diluted batch was labeled as 10CGW2E (Actual total weight of diluted batch = 458.32 g (which rounds to 0.5% NaOCl, the LCL)
4. Characterization of 10CGW2E gave titration results at 0.506% NaOCl. The batch was sub-divided and labeled as sample #s 10CGW2E-1 thru -5. Two samples of the aged lot # 10CGW2 were shipped to BioScience Laboratories for micro efficacy testing—sample canister #10CGW2-5 and diluted sample #10CGW2E-5. Note—10CGW2-5 refers to the canister; the designations with E and L refers to the liquid extracted from the wipe; see further explanation under "e) identify the aged lot".

Registrant's Response to (d). This contract testing lab (BioScience Laboratories) routinely uses 0.45 µm for such applications since 0.45 µm is widely accepted for the growth of microorganisms and a study by Millipore (document attached) has confirmed that this size is the most appropriate for general microbiological purposes and recovery across a variety of test organisms. Moreover, loss of Clostridium difficile spores through the 0.45 µm filter is not expected to occur since C. difficile spores have been shown to be approximately 2.0 µm long and 1.1 µm wide (Panessa-Warren et. al. Tissue & Cell, 1997, 29 (4), 449-461. Additionally this pore size also helps to ensure adequate passage of nutrients from the media through the filter for growth of microorganisms.

Registrant's Response to (e). The aged lot is lot # 10CGW2 and is listed on the study as Lot Number 10CGW2 (> 60 days old) which includes both

1. Test Solution #1 (10CGW2L) and
2. Test Solution #2 (10CGW2E)

Note—L means the lab extracted the lotion from the wipe and E means Clorox extracted the lotion from the wipe.

Agency's Final Response to Conclusion1. According to the information provided, the registrant has tested the appropriate number of test lots, to include an aged lot (> 60 days old). No additional information is required concerning the issues concern Conclusion #1 (a), (b), (c), (d), and (e).

Agency's Conclusion 2. The data package failed to include a wetness determination study to justify/determine the contact time. The study is required to determine the acceptability of the proposed claims.

Registrant Response to 2. Regarding the wetness determination study, we submitted this study with our original submission (assigned MRID No. 48090001) under this PRIA action. According to the DER dated August 29, 2010, the study was acceptable. This cited study was inadvertently omitted from the data matrix we submitted February 2011; we are submitting revised data matrices (Agency & public copies) along with the Certification with Respect to Citation of Data. Although the wetness determination was conducted on a different formula (F2004.0147), the only difference between these two formulas is the F2004.0147 has an additional ingredient present at 0.02%.

Agency's Final Response to Conclusion 2. The Agency requires wetness determination of the product in question, in order to determine its acceptability. Citing the study from a different formulation is unacceptable.