**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, DC 20460**

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

May 12, 2005

**MEMORANDUM**

**Subject:** Efficacy Review for Peridox™, EPA File Symbol 81073-R; DP Barcode: D313282

**From:** Ibrahim Laniyan, Microbiologist
Product Science Branch
Antimicrobials Division (7510C)

**Thru:** Nancy Whyte, Acting Team Leader
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

**To:** Tony Kish / Marshall Swindell
Regulatory Management Branch I
Antimicrobials Division (7510C)

**Applicant:** Clean Earth Technologies, LLC
13378 Lakefront Drive
St. Louis, MO 63045

TB Claim
OK as
being referenced
for 81073-G

**Formulation from the Label:**

| Active Ingredient(s) | % by wt. |
|---|---|
| Hydrogen Peroxide | 24.0 % |
| Peroxyacetic Acid | 1.2 % |
| Other ingredients | 74.8 % |
| Total | 100.0 % |

## I. BACKGROUND

The product, Peridox™ (EPA File Symbol 81073-R), is a new product. The applicant requested to register the product as a disinfectant (bactericide, virucide, tuberculocide, fungicide), sanitizer for non-food contact surfaces, and sanitizing rinse for previously cleaned, food contact surfaces. The applicant also requested to register the product as a sterilant of manufacturing, filling and packaging equipment in aseptic processes. The product is for use on hard, non-porous surfaces in institutional, industrial, animal care, and hospital or medical environments. The label claims that the product is effective in the presence of 250 ppm hard water. Bactericidal, virucidal, tuberculocidal, fungicidal, and sterilant efficacy is claimed in the presence of an organic soil load. Studies were conducted at MicroBioTest, Inc., located at 105B Carpenter Drive in Sterling, VA 20164; and ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained letters from the applicant's representative to EPA (dated October 19, 2004 and January 26, 2005), EPA Form 8570-4 (Confidential Statement of Formula), 19 studies (MRID Nos. 464561-08 through 464561-26), Statements of No Data Confidentiality Claims for all 19 studies, and the proposed label.

Note: Because the applicant had not decided on the name of the product at the time of efficacy testing, Peridox™ was called: CET PS1'B, CET PS1B, PS1B, PS1'B, and 24% PS1B (see letter from the applicant dated May 5, 2005)

## II. USE DIRECTIONS

The product is designed to be used as a sterilant on previously cleaned, hard, non-porous surfaces such as processing surfaces. Directions on the proposed label provided the following information regarding preparation and use of the product as a sterilant: Remove gross particles. Wash with a detergent solution. Rinse with potable water. Prepare a 4% use solution. Circulate, coarse spray, or flood the surface to be treated with the use solution. Allow surfaces to remain wet for 45 minutes. Thoroughly rinse food contact surfaces with sterile water or potable rinse. This product is not for use as a sterilant on medical devices.

The product is designed to be used for disinfecting hard, non-porous surfaces such as floors, walls, shower stalls, benches, bath mats, and processing equipment. Directions on the proposed label provided the following information regarding preparation and use of the product as a:

> Bactericidal disinfectant: For heavily soiled areas, a pre-cleaning step is required. Prepare a use solution by adding 26 ounces of the product to 2 gallons of water (a 1:10 dilution; a 2% $H_2O_2$ concentration). Apply the use solution using a spray applicator device. Wet all surfaces thoroughly. Allow surfaces to remain wet for 5 minutes. Remove solution and entrapped soil with a clean cloth.
>
> Virucidal disinfectant or as a disinfectant against *Mycobacterium bovis*: Prepare a use solution by adding 51 ounces of the product to 2 gallons of water (1:5 dilution; a 4% $H_2O_2$ concentration). Apply the use solution using a spray applicator device. Wet all surfaces thoroughly. Allow surfaces to remain wet for 10 minutes (30 minutes for Poliovirus and Hepatitis A virus). **[The directions did not mention the need to pre-clean heavily soiled areas.] [The directions did not mention if, and how, the product should be removed**

**from treated surfaces.]**

Fungicidal disinfectant: Prepare a use solution by adding 6.5 ounces of the product to 2 gallons of water (1:39 dilution; a 0.5% $H_2O_2$ concentration). Apply the use solution using a spray applicator device. Wet all surfaces thoroughly. Allow surfaces to remain wet for 10 minutes. **[The directions did not mention the need to pre-clean heavily soiled areas.] [The directions did not mention if, and how, the product should be removed from treated surfaces.]**

The product is designed to be used as a sanitizing rinse on previously cleaned, hard, non-porous, food contact surfaces such as equipment, pipelines, tanks, vats, fillers, and evaporators. Directions on the proposed label provided the following information regarding preparation and use of the product as a sanitizing rinse Prepare a use solution by adding 26 ounces of the product to 2 gallons of water (1:10 dilution; a 2% $H_2O_2$ concentration). Allow surfaces to remain wet for 30 seconds. **[The directions did not mention the need to pre-clean surfaces by washing with a detergent and rinsing with potable water.] [The directions did not specify how the use solution should be applied.] [The directions did not mention if, and how, the product should be removed from treated surfaces.]**

The product is also designed to be used as a sanitizer on previously cleaned, hard, non-porous, non-food contact surfaces such as floors, walls, tables, chairs, benches, drains, troughs, and drip pans. Directions on the proposed label provided the following information regarding preparation and use of the product as a sanitizer: Remove gross particles. Wash with a detergent solution. Rinse with potable water. Prepare a use solution by adding 26 ounces of the product to 2 gallons of water (1:10 dilution; a 2% $H_2O_2$ concentration). **[The directions did not specify how the use solution should be applied.] [The directions did not specify a contact time.] [The directions did not mention if, and how, the product should be removed from treated surfaces.]**

## III. AGENCY STANDARD FOR PROPOSED CLAIMS

**Sterilizers:** The AOAC Sporicidal Test is required for substantiating sterilizing claims. The following information applies to all products represented as sporicidal or sterilizing agents. Sixty carriers, representing each of 2 types of surfaces (porcelain penicylinders and silk suture loops), must be tested against spores of both *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) on 3 product samples representing 3 different batches, one of which is at least 60 days old (240 carriers per sample; a total of 720 carriers). Any sterilizing agent (liquid, vapor, or gas) that is recommended for use in a specific device must be tested by the AOAC Sporicidal Test in that specific device and according to the directions for use. **Performance Standard:** Killing on all of the 720 carriers is required; no failures are permitted. Data to support sterilizing claims must be confirmed by tests conducted by a second, independent laboratory of the applicant's choice (other than the laboratory that developed the original data). The following minimal confirmatory data must be developed on one sample of the product: Thirty carriers with each of the 2 types of surfaces (silk suture loops and porcelain penicylinders) against spores of both *Bacillus subtilis* and *Clostridium sporogenes* (a total of 120 carriers) by the AOAC Sporicidal Test. These Agency standards are presented in DIS/TSS-9.

**Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments - Efficacy data**

**requirements for hospital and general disinfectant uses:** The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments 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 products). Sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). **Performance requirements:** To support products represented in labeling as "disinfectants", killing on 59 out of each set of 60 carriers is required to provide effectiveness at the 95% confidence level. The above Agency standards are presented in DIS/TSS-1.

**Disinfectants for Use in Hospital or Medical Environments – Additional Microorganisms (Bactericidal requirements):** Effectiveness of disinfectants against specific microorganisms 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, but not including viruses, 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 samples, representing 2 different batches. **Performance requirements:** To support products labeled as "disinfectants" for specific microorganisms (other than those microorganisms named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data, on appropriate culture media, must be submitted on each test microorganism to demonstrate that a concentration of at least $10^4$ microorganisms survived the carrier-drying step. These Agency standards are presented in DIS/TSS-1.

**Disinfectants for Use as Tuberculocides (Using the AOAC Tuberculocidal Activity Test Method or the AOAC Germicidal Spray Products 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. Products may be tested using one of four recommended methods: the AOAC Tuberculocidal Test Method, Tuberculocidal Activity of Disinfectants Test Method with significant modification of the standard test conditions of contact time and/or temperature, Quantitative Tuberculocidal Activity Test Method, and AOAC Germicidal Spray Products Test Method.

When using the existing or modified AOAC Tuberculocidal Activity Test Methods, or the AOAC Germicidal Spray Products Test Method, ten (10) carriers for each of two samples, representing two different batches of product, must be tested against *Mycobacterium bovis* BCG (a member of the *Mycobacterium tuberculosis* species complex). When using the existing or modified AOAC Tuberculocidal Activity Test Method, or the AOAC Germicidal Spray Products Test Method, killing on all carriers/slides as demonstrated in Modified Proskauer-Beck Broth, and no growth in any of the inoculated tubes of two additional media (i.e., Middlebrook 7H9 Broth Difco B, Kirchners Medium, and/or TB Broth Base) is required. When using Quantitative Tuberculocidal Activity Test Method, the test product must be able to demonstrate at least a 4-log reduction of *Mycobacterium bovis*. Agency standards are presented in EPA DIS/TSS-6, Subdivision G Guidelines, and "EPA Data Call-in Notice for Tuberculocidal Claims," dated June 13, 1986.

**Fungicidal requirements:** Effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data derived from each of 2 samples representing 2 different batches using the AOAC Fungicidal Test. **Performance standard.** The highest dilution that kills all fungal spores is the minimum effective concentration.

Alternatively, the AOAC Use Dilution Method, modified to conform with appropriate elements in the AOAC Fungicidal Test, may be employed. If the product is intended for use as a spray, the AOAC Germicidal Spray Products Test must be employed. The inoculum in the above tests must be modified to provide a concentration of at least $10^6$ conidia per carrier. Ten carriers on each of 2 samples representing 2 different batches must be employed in the test. **Performance requirements:** Killing of the test microorganism on all carriers is required. The above Agency standards are presented in DIS/TSS-06.

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

**Virucidal requirements:** 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 the AOAC Use-Dilution Method (for liquid disinfectants) must be used in developing data for virucides intended for use upon dry inanimate, environmental surfaces (e.g., floors, tables, cleaned dried medical instruments). 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 batches of disinfectant must be tested against a recoverable virus titer of at least $10^4$ from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. **Performance standard:** For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

**Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces):** Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned, food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 1 sample from each of 3 different product lots, one of which is at least 60 days old against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at the hard water tolerance claimed. **Performance requirements:** Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and 125 x $10^6$/ml for percent reductions to be considered valid. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution from the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances. These Agency standards are presented in DIS/TSS-4 and -17, as well as the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method..

**Sanitizers for Non-Food Contact Surfaces:** The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different batches, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). **Performance requirements:** The results must show a bacterial reduction of at least 99.9% over the parallel control count within 5 minutes. These Agency standards are presented in DIS/TSS-10.

**Sanitizers for Non-Food Contact Surfaces - Additional Microorganisms:** There are cases where an applicant requests to make claims of effectiveness against additional microorganisms for a product that is already registered as a sanitizing rinse for non-food contact surfaces. The Agency DIS/TSS guidance is silent on this matter and that confirmatory test standards would apply. For sanitizing rinses for non-food contact surfaces, 2 product samples, representing 2 different batches, must be tested against each additional microorganism. **Performance standard:** The results must show a bacterial reduction of at least 99.9% over the parallel control count within 5 minutes. These Agency standards are presented in DIS/TSS-10.

**Supplemental Recommendations:** An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5% blood serum. The organic soil level suggested is considered appropriate for simulating lightly or moderately soiled surface conditions. When the surface to be treated has heavy soil deposits, a cleaning step must be recommended prior to application of the antimicrobial agent. The effectiveness of antimicrobial agents must be demonstrated in the presence of a specific organic soil at an appropriate concentration level when specifically claimed and/or indicated by the pattern of use. The hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish disinfectant efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. All products tested by the recommended methods may be tested at the exposure periods prescribed in those methods. When an antimicrobial agent is intended to be effective in treating a non-porous surface, the Recommended Methods simulate this condition by using non-porous surface carrier (stainless steel cylinder or glass slide) specified in the method. The exposure period or manner of use necessary to provide efficacy must be featured prominently on the product label. These Agency standards are presented in DIS/TSS-2.

## IV. BRIEF DESCRIPTION OF THE DATA

**1. MRID 464561-08 "AOAC Germicidal Spray Test" for CET PS1'B, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – June 21, 2004. Amended report date – September 8, 2004. Laboratory Project Identification Number 534-104.**

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538), and *Salmonella choleraesuis* (ATCC 10708). Three lots (Lot Nos. CET051904SI002, CET043004FG008, and CET120903FG003) of the product, CET PS1'B, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. At least one of the product lots tested (i.e., Lot No. CET120903FG003) was at least 60 days old at the time of testing. A 1:12 use solution of the product was prepared using 250ppm AOAC synthetic hard water (titration results not provided; yielding 2% $H_2O_2$). Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01-0.03 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 20-40 minutes at 37±2°C. For each lot of product, separate carriers were sprayed at a distance of 8-12 inches until the carrier surfaces were thoroughly wet. Each carrier was exposed to the use solution for 5 minutes at 22°C. Following exposure, excess liquid was allowed to drain from the carriers. The carriers were transferred to tubes of D/E Neutralizing Broth containing 0.3% Thioglycolic acid and Catalase (0.03 ml of 1% Catalase per 20 ml of neutralizer) to neutralize. All subcultures were incubated for 48±2 hours at 37±2°C, and then examined for the presence or absence of visible growth. Controls included those for sterility, viability, neutralizer effectiveness, bacteriostasis, carrier population, and confirmation of the challenge microorganisms. The reported average colony forming units (CFU) per dried carrier, for each test microorganism, are as follows: ***Pseudomonas aeruginosa*** **$1.4 \times 10^6$**, ***Staphylococcus aureus*** **$2.4 \times 10^6$**, ***Salmonella choleraesuis*** **$3.7 \times 10^5$**.

Note: The original report was amended to include more details about the study (e.g., manufacture dates of the product lots, hydrogen peroxide concentration, product evaluation criteria).

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

**2. MRID 464561-09 "AOAC Use Dilution Test, Healthcare" for CET PS1'B, by Donna B. Suchmann. Study conducted at MicroBioTest, Inc. Study completion date – June 28, 2004. Amended report date – September 8, 2004. Laboratory Project Identification Number 535-106.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538), *Salmonella choleraesuis* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. CET051904SI002, CET043004FG008, and CET120903FG003) of the product, CET PS1'B, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. At least one of the product lots tested (i.e., Lot No. CET120903FG003) was at least 60 days old at the time of testing. A 1:12 use solution of the product was prepared using 250 ppm AOAC synthetic hard water (titration results not provided; yielding 2% $H_2O_2$). Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed in a 48-54 hour old suspension of the test organism, at a ratio of 20 carriers per 20 ml of broth. The carriers were dried for 20-40 minutes at 37±2°C. Each carrier

was exposed to 10 ml of the use solution for 5 minutes at 20°C. The carriers were transferred to tubes of D/E Neutralizing Broth containing 0.3% Thioglycolic acid and Catalase (0.03 ml of 1% Catalase per 10 ml of neutralizer) to neutralize. All subcultures were incubated for 48±2 hours at 37±2°C, and then examined for the presence or absence of visible growth. Controls included those for sterility, viability, neutralizer effectiveness, bacteriostasis, carrier counts, and confirmation of the challenge microorganisms. The reported average colony forming units (CFU) per dried carrier, for each test microorganism, are as follows: ***Pseudomonas aeruginosa* $2.0 \times 10^5$, *Staphylococcus aureus* $6.5 \times 10^4$, *Salmonella choleraesuis* $6.2 \times 10^4$.**

Note: The original report was amended to include more details about the study (e.g., manufacture dates of the product lots, hydrogen peroxide concentration, product evaluation criteria).

**3. MRID 464561-10 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organisms: *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538)" for PS1B, by Sally Nada. Study conducted at ATS Labs. Study completion date – October 5, 2004. Project Number A02401.**

This study was conducted against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. CET051204SI001, CET070904SI003, and CET051904SI002) of the product, PS1B, were tested using the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. At least one of the product lots tested (i.e., Lot No. CET051904SI002) was at least 60 days old at the time of testing. A 1:12 use solution of the product was prepared using 250 ppm AOAC synthetic hard water (titrated at 249 ppm; yielding 2% $H_2O_2$). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. A 99-ml aliquot of the use solution was transferred to a sterile, 250-ml Erlenmeyer flask and placed in a water bath at 25±1°C. A one-ml bacterial suspension was added to each flask. One-ml aliquots of the bacterium-product mixture were transferred to 9.0 ml of Letheen Broth containing 0.07% Lecithin, 0.5% Tween 80, and 0.05% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 ml and four 0.1 ml aliquots of the neutralized mixture were plated in tryptone glucose extract agar. All plates were incubated for 48±4 hours at 35-37°C and the colonies were counted. Controls included those for purity, numbers count, viability, neutralization confirmation, and sterility. The reported average initial CFU/ml, for each test microorganism, are as follows: ***Escherichia coli* $1.24 \times 10^8$, *Staphylococcus aureus* $1.1 \times 10^8$**

Note: The applicant provided the data for a failed trial set up on September 10, 2004. In that trial, the neutralization confirmation control did not meet the acceptance criterion. Thus, the test was invalid. These data were not used to evaluate efficacy of the test product. See Attachment I of the laboratory report.

**4. MRID 464561-11 "AOAC Tuberculocidal Activity of Disinfectants" for CET PS1'B, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – October 11, 2004. Laboratory Project Identification Number 535-108.**

This study was conducted against *Mycobacterium bovis* BCG. Two lots (Lot Nos. CET051904SI002 and CET043004FG008) of the product, CET PS1'B, were tested using the AOAC Confirmative in vitro Test for Determining Tuberculocidal Activity Method (modified) as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. A 1:6 use solution of the product was prepared using 250 ppm hard water (titration results not provided; yielding 4% $H_2O_2$). Heat-

inactivated horse serum was added to the inoculum to achieve a 5% organic soil load. Ten (10) porcelain penicylinder carriers were immersed in a 14-25 day old suspension of the test organism, at a ratio of 10 carriers per 15-20 ml of inoculum. The carriers were dried in an incubator for 30 minutes at 37±2°C. Each carrier was exposed to 10 ml of the use solution for 10 minutes at 20°C. After the contact period, individual carriers were neutralized in 10 ml of D/E Neutralizing Broth containing 0.3% Thioglycolic acid and Catalase (0.03 ml of 1% Catalase per 10 ml of neutralizer). After 10 minutes in the neutralizer, each carrier was transferred to 20 ml of Modified Proskauer-Beck Medium. From each tube of neutralizer, 2 ml was subcultured to each of the two remaining recovery media – Kirchner's Medium and Middlebrook 7H9. Subcultures were incubated for 60 days at 37±2°C and then observed for the presence or absence of growth. Incubation was continued for an additional 30 days because no growth was observed and the subcultures were again observed for the presence or absence of growth. Controls included those for viability, neutralizer effectiveness, sterility, carrier counts, and confirmation of the challenge microorganism. The reported average Colony Forming Units (CFU) per carrier, for the test microorganism, is: ***Mycobacterium bovis*** **BCG 1.6 x $10^5$**.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

**5. MRID 464561-12 "Virucidal Efficacy Test, Influenza virus H3N2" for CET PS1B, by M. Khalid Ijaz. Study conducted at MicroBioTest, Inc. Study completion date – October 15, 2004. Laboratory Project Identification Number 535-110.**

This study was conducted against Influenza virus type A (Strain Hong Kong/8/68(H3N2); obtained from Charles River Laboratories), using embryonated chicken eggs (obtained from B&E Eggs) as the host system. Three lots (Lot Nos. CET051904SI002, CET043004FG008, and CET051204SI001) of the product, CET PS1B, were tested. The study protocol followed MicroBioTest Protocol "Virucidal Efficacy Test, Influenza virus H3N2," dated May 17, 2004 (copy provided). A 1:6 use solution of the product was prepared using sterile deionized water (yielding 4% $H_2O_2$). The stock virus culture contained a 5% organic soil load (serum not specified). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried at room temperature for 30-60 minutes. For each lot of product, separate dried virus films were sprayed for **4** seconds at a distance of 10 inches from the carrier surface. The virus films remained exposed to the use solution for 10 minutes at 22°C. After exposure, 2.0 ml of fetal bovine serum with 0.3% sodium thiosulfate was added to neutralize. The plates were scraped with a cell scraper to re-suspend the contents. The neutralized mixture was passed through a Sephacryl column, and diluted serially in Earle's Balanced Salt Solution. Embryonated eggs were inoculated intra-allantoically in quadruplicate with 0.2 ml of the dilutions. One day post-inoculation, all eggs were candled and dead embryos were discarded. The eggs were incubated for a total of 5-7 days at 37±2°C, candled again, and then stored at 2±2°C overnight. Afterwards, the allantoic fluid was harvested and kept at 2±2°C until assay using a hemagglutination assay. Controls included those for toxicity, toxicity-related viral interference, plate recovery, column titer, virus stock titer, host viability, and neutralizer effectiveness. The 50% embryo lethal dose/ embryo infectious dose per ml (ELD/$EID_{50}$/ml) was determined using the method of Reed and Muench. The titer of the plate recovery control was **6.0** $\log_{10}$. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥4.5** $\log_{10}$ for all three batches.

Note: The study was conducted according to GLP standards with the following exception: "Prior to

the study, the measured output from the spray product was not promptly documented in the data pack."

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

**6. MRID 464561-13 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Reovirus" for PS1B, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – October 28, 2004. Project Number A02490.**

This study was conducted against Reovirus (Strain Abney; ATCC VR-232), using LLC-$MK_2$ cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc.) as the host system. Two lots (Lot Nos. CET051904SI002 and CET070904SI003) of the product, PS1B, were tested according to ATS Labs Protocol No. CTL01071204.REO (copy not provided). A 1:6 use solution of the product was prepared using 250 ppm AOAC synthetic hard water (titrated at 252 ppm; yielding 4% $H_2O_2$). The stock virus culture contained a 5% organic soil load (fetal bovine serum). 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 air-dried at 20.0°C for 20 minutes at 36% relative humidity. For each lot of product, separate dried virus films were sprayed at a distance of 8-12 inches until the carrier surfaces were visibly wet. The virus films were completely covered with the use solution, and remained exposed to the use solution for **10** minutes at 20°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. LLC-$MK_2$ cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **6.25 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥5.75 $\log_{10}$** for both batches.

**7. MRID 464561-14 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Human Coronavirus" for PS1B, by Karen M. Ramm. Study conducted at ATS Labs. Study completion date – December 8, 2004. Project Number A02489.**

This study was conducted against Human coronavirus (Strain 229E; ATCC VR-740), using MRC-5 cells (human embryonic lung cells; propagated in-house; originally obtained from ATCC) as the host system. Two lots (Lot Nos. CET051904SI002 and CET070904SI003) of the product, PS1B, were tested according to ATS Labs Protocol No. CTL01071204.HCV (copy not provided). A 1:6 use solution of the product was prepared using 250 ppm AOAC synthetic hard water (titrated at 252 ppm; yielding 4% $H_2O_2$). The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). 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 air-dried at 20.1°C for 20 minutes at 41% relative humidity. For each lot of product, separate dried virus films were sprayed at a distance of 8-12 inches until the carrier surfaces were visibly wet. The virus films were completely

covered with the use solution, and remained exposed to the use solution for 10 minutes at 20.1°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 2% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. MRC-5 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% $CO_2$ and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **4.5 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥3.0 $\log_{10}$** for both batches.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: The applicant provided the data for a failed trial set up on October 20, 2004. In that trial, the dried virus control was not at least $10^4$. Thus, the test was invalid. These data were not used to evaluate efficacy of the test product. See Attachment I of the laboratory report.

**8. MRID 464561-15 "Sporicidal Activity of Disinfectants, Test Organisms: *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584)" for 24% PS1B, by Amy S. Jeske. Study conducted at ATS Labs. Study completion date – November 29, 2004. Project Number A02491.**

This study was conducted against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584). Three lots (Lot Nos. CET092304SI004, CET092304SI005, and CET051904SI002) of the product, 24% PS1B, were tested using the AOAC Sporicidal Activity of Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. At least one of the product lots tested (i.e., Lot No. CET051904SI002) was at least 60 days old at the time of testing. A 1:6 use solution of the product was prepared using 250 ppm AOAC synthetic hard water (titrated at 248 and 252 ppm; yielding 4% $H_2O_2$). Fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. Sixty (60) porcelain penicylinder carriers and silk suture loops were immersed in a 72±4 hour old broth culture, at a ratio of 1 carrier per 1 ml of broth culture. The carriers were dried in a vacuum desiccator. The *Bacillus subtilis* carriers were dried for 2 days, and the *Clostridium sporogenes* carriers were dried for 3 days. Individual carriers were exposed to 10 ml of the use solution for 45 minutes at 19-20°C. After the exposure period, individual carriers were transferred to tubes containing 10 ml of Letheen Broth with 0.07% Lecithin, 0.5% Tween 80, and 0.05% Catalase to neutralize. After completion of the subcultures, carriers were transferred to secondary subculture tubes containing Fluid Thioglycollate Medium. Subcultures were incubated for 21 days at 35-37°C. Tubes were heat-shocked for 20 minutes at 80±2°C and re-incubated for 72±4 hours at 35-37°C. Tubes were refrigerated at 2-8°C for 1-2 days and then observed for the presence or absence of visible growth. Controls included those for purity, sterility, viability, carrier quantitation, neutralization confirmation, and acid resistance at 2, 5, 10, and 20 minutes. The reported titers per inoculated carriers are: ***Bacillus subtilis* on Suture Loops $6.1 \times 10^4$, *Bacillus subtilis* on Penicylinders $1.7 \times 10^4$, *Clostridium sporogenes* on Suture Loops $8.1 \times 10^5$, *Clostridium sporogenes* on Penicylinders $1.56 \times 10^6$.**

**9. MRID 464561-16 "Confirmatory Sporicidal Test" for CET PS1'B, by Angela L.**

**Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – January 4, 2005. Laboratory Project Identification Number 535-114.**

This study was conducted against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584). One lot (Lot No. CET092304SI004) of the product, CET PS1'B, was tested using the AOAC Sporicidal Activity of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. A 1:6 use solution of the product was prepared using 250 ppm AOAC hard water (titration results not provided; yielding 4% $H_2O_2$). Thirty (30) porcelain penicylinder carriers and silk suture loops were contaminated with the test organism. The carriers were dried in a vacuum desiccator for at least 24 hours. Each carrier was exposed to 10 ml of the use solution for 45 minutes at 20°C. After the exposure period, individual carriers were transferred to tubes containing D/E Neutralizing Broth with 0.3% Thioglycolic acid and Catalase (0.03 ml of 1% Catalase added per 10 ml of neutralizer) to neutralize. After completion of the subcultures, carriers were transferred to secondary subculture tubes containing Fluid Thioglycollate Medium. Subcultures were incubated for 21 days at 37±2°C. Tubes were heat-shocked for 20 minutes at 80±1°C and re-incubated for 72±2 hours at 37±2°C. All tubes were then observed for the presence or absence of growth. Controls included those for sterility, viability, carrier quantitation, neutralizer effectiveness, confirmation of the challenge microorganisms, and acid resistance at 2, 5, 10, and 20 minutes. The pre-test inoculum counts averaged: ***Bacillus subtilis* 7.3x10$^6$, and *Clostridium sporogenes* 4.2x10$^6$.**

Note: The study was conducted according to GLP standards with the following exceptions: "Chloroform used for suture preparation was expired by 7 days, and a pH reading was not documented during suture preparation."

**10. MRID 464561-17 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Hepatitis A virus" for PS1B, by Karen M. Ramm. Study conducted at ATS Labs. Study completion date – December 2, 2004. Project Number A02501.**

This study was conducted against Hepatitis A virus (Strain HM-175; obtained from AppTec Laboratory Services, Camden, NJ), using FRhK-4 cells (fetal Rhesus monkey kidney cells; ATCC CRL-1688; propagated in-house; originally obtained from ATCC) as the host system. Two lots (Lot Nos. CET051904SI002 and CET070904SI003) of the product, PS1B, were tested according to ATS Labs Protocol No. CTL01071204.HAV (copy not provided). A 1:6 use solution of the product was prepared using 250 ppm AOAC synthetic hard water (titrated at 256 ppm; yielding 4% $H_2O_2$). The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). 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 air-dried at 20°C at 37% relative humidity for 20 minutes. For each lot of product, separate dried virus films were sprayed (10 pumps) at a distance of 8-12 inches until the carrier surfaces were visibly wet. The virus films were completely covered with the use solution, and remained exposed to the use solution for **30 minutes** at 20.0-20.1°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 10% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, 2.5 µg/ml amphotericin B, and 2.0 mM L-glutamine. FRhK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were allowed to adsorb for ≥90 minutes at 36-38°C in a humidified atmosphere of 5-7% $CO_2$. Following adsorption, 1.0 ml of test medium was added to each well. The cultures were incubated at 36-38°C

in a humidified atmosphere of 5-7% $CO_2$ and scored periodically for 15 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **7.5 $log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥7.0 $log_{10}$** for both batches.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

**11. MRID 464561-18 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Avian Influenza A (Influenza A Reassortant)" for PS1B, by Karen M. Ramm. Study conducted at ATS Labs. Study completion date – November 3, 2004. Project Number A02402.**

This study was conducted against Avian Influenza A (Strain A/Washington/897/80 X A/Mallard/New York/6750/78; ATCC VR-2072), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc.) as the host system. Two lots (Lot Nos. CET051904SI002 and CET070904SI003) of the product, PS1B, were tested according to ATS Labs Protocol No. CTL01073004.AFLU (copy not provided). A 1:6 use solution of the product was prepared using 250 ppm AOAC synthetic hard water (titrated at 253 ppm; yielding 4% $H_2O_2$). The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). 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 air-dried at 20°C at 37% relative humidity for 20 minutes. For each lot of product, separate dried virus films were sprayed (12 pumps) at a distance of 8-12 inches until the carrier surfaces were visibly wet. The virus films were completely covered with the use solution, and remained exposed to the use solution for 10 minutes at 20°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.75 $log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥4.25 $log_{10}$** for both batches.

**12. MRID 464561-19 "Virucidal Efficacy Test, Influenza virus B" for CET PS1'B, by M. Khalid Ijaz. Study conducted at MicroBioTest, Inc. Study completion date – October 27, 2004. Laboratory Project Identification Number 535-111.**

This study was conducted against Influenza virus B (strain not specified; obtained from Charles River Laboratories), using embryonated chicken eggs (obtained from B&E Eggs) as the host system. Three lots (Lot Nos. CET051904SI002, CET043004FG008, and CET051204SI001) of the product, CET PS1'B, were tested. The study protocol followed MicroBioTest Protocol "Virucidal Efficacy Test, Influenza virus B," dated May 17, 2004 (copy not provided). A 1:6 use solution of the product was prepared using sterile deionized water (yielding 4% $H_2O_2$). The stock virus culture contained at least a 5% organic soil load (serum not specified). Films of virus were prepared by

spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried at room temperature for 30-60 minutes. For each lot of product, separate dried virus films were sprayed for 4 seconds at a distance of 10 inches from the carrier surface. The virus films remained exposed to the use solution for 10 minutes at 22°C. After exposure, 2.0 ml of fetal bovine serum with 0.3% sodium thiosulfate was added to neutralize. The plates were scraped with a cell scraper to re-suspend the contents. The neutralized mixture was passed through a Sephacryl column, and diluted serially in Earle's Balanced Salt Solution. Embryonated eggs were inoculated intra-allantoically in quadruplicate with 0.2 ml of the dilutions. One day post-inoculation, all eggs were candled and dead embryos were discarded. The eggs were incubated for a total of 5-7 days at 37±2°C, candled again, and then stored at 2±2°C overnight. Afterwards, the allantoic fluid was harvested and kept at 2±2°C until assay using a hemagglutination assay. Controls included those for toxicity, plate recovery, column titer, virus stock titer, toxicity-related viral interference control, host viability, and neutralizer effectiveness. The 50% embryo lethal dose/ embryo infectious dose per ml (ELD/EID$_{50}$/ml) was determined using the method of Reed and Muench. The titer of the plate recovery control was **6.0 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥4.5 $\log_{10}$** for all three batches.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

**13. MRID 464561-20 "AOAC Germicidal Spray Test Using Fungi" for CET PS1'B, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – July 12, 2004. Amended report date – September 8, 2004. Laboratory Project Identification Number 535-107.**

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot Nos. CET051904SI002 and CET043004FG008) of the product, CET PS1'B, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16$^{th}$ Edition, 1995. A 1:48 use solution of the product was prepared using 250 ppm AOAC synthetic hard water (titration results not provided; yielding 0.5% $H_2O_2$). Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 10-15 day old suspension of the test organism. The carriers were dried for 30-40 minutes at 37±2°C. For each lot of product, separate carriers were sprayed at a distance of 8-12 inches until the carrier surfaces were thoroughly wet. Each carrier was exposed to the use solution for 10 minutes at 24°C. Following exposure, excess liquid was allowed to drain from the carriers. The carriers were transferred to tubes of Neopeptone Glucose Broth with 0.25% yeast extract, 0.3% sodium thioglycollate, 0.6% sodium thiosulfate, 0.5% Polysorbate 80, 0.7% Lecithin, and Catalase (0.3 ml of 1% Catalase per 20 ml of neutralizer) to neutralize. All subcultures were incubated for 10 days at 25-30°C. After incubation, the subcultures were streaked onto Neopeptone glucose agar plates. The plates were incubated for 3-5 days at 25-30°C, and then examined for the presence or absence of visible growth. Controls included those for sterility, viability, neutralizer effectiveness, carrier count, and confirmation of the challenge microorganism. The reported average carrier count was: ***Trichophyton mentagrophyte* 2.7 x 10$^4$**.

Note: The original report was amended to include more details about the study (e.g., manufacture dates of the product lots, hydrogen peroxide concentration, product evaluation criteria).

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

**14. MRID 464561-21 "Virucidal Efficacy Test, Poliovirus" for PS1'B, by M. Khalid Ijaz. Study conducted at MicroBioTest, Inc. Study completion date – November 11, 2004. Laboratory Project Identification Number 535-112.**

This study was conducted against Poliovirus type 1 (ATCC VR-192), using Vero cells (ATCC CCL-81) as the host system. Three lots (Lot Nos. CET051204SI001, CET051904SI002, and CET070904SI003) of the product, PS1'B, were tested. The study protocol followed MicroBioTest Protocol "Virucidal Efficacy Test, Poliovirus" dated August 24, 2004 (copy provided). A 1:6 use solution of the product was prepared using sterile deionized water (yielding 4% $H_2O_2$). The stock virus culture contained at least a 5% organic soil load (serum not specified). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried at room temperature for 30-60 minutes. For each lot of product, separate dried virus films were sprayed for 4 seconds at a distance of 8 inches from the carrier surface. The virus films remained exposed to the use solution for **30 minutes** at 22°C. After exposure, 2.0 ml of fetal bovine serum with 0.3% sodium thiosulfate was added to neutralize. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was diluted serially in M-199 supplemented with 10% fetal bovine serum. Vero cells were inoculated in quadruplicate with an unspecified amount of the dilutions. The cultures were allowed to adsorb for 60-90 minutes at 37±2°C in 5±1% $CO_2$. Following adsorption, the plates were aspirated, washed, and overlaid with cell culture medium. The cultures were incubated for 5-7 days at 37±2°C in 5±1% $CO_2$. Post-incubation, the cultures were scored for the presence or absence of unspecified cytopathic effects. Controls included those for cytotoxicity, cytotoxicity-related viral interference, plate recovery, virus stock titer, cell viability, and neutralizer effectiveness. The 50% cell culture infectious dose per ml ($CCID_{50}$/ml) was determined using the method of Reed and Muench. The titer of the plate recovery control was **6.0 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥2.5 $\log_{10}$** for all three batches.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

**15. MRID 464561-22 "AOAC Germicidal Spray Method, Test Organism: *Salmonella typhimurium* (ATCC 23564)" for PS1B, by Amy Jeske. Study conducted at ATS Labs. Study completion date – December 22, 2004. Project Number A02585.**

This study was conducted against *Salmonella typhimurium* (ATCC 23564). Two lots (Lot Nos. CET092304SI004 and CET092304SI005) of the product, PS1B, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. A 1:12 use solution of the product was prepared using 250 ppm AOAC synthetic hard water (titrated at 253 ppm; yielding 2% $H_2O_2$). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 mL of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were sprayed at a distance of 8-12 inches until the carrier surfaces were visibly wet. Each carrier was exposed to the use solution for 5 minutes at 21°C at 4.3% relative humidity. Following exposure, the remaining liquid was allowed to drain from the carriers. The carriers were transferred to 20 ml of Letheen Broth with 0.07% Lecithin, 0.5% Tween 80, and 0.05% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier

population. The reported colony forming units per carrier population control is ***Salmonella typhimurium*** **8.3 x $10^4$**.

**16. MRID 464561-23 "AOAC Germicidal Spray Method, Test Organism: *Enterobacter aerogenes* (ATCC 15038)" for PS1B, by Amy Jeske. Study conducted at ATS Labs. Study completion date – December 21, 2004. Project Number A02584.**

This study was conducted against *Enterobacter aerogenes* (ATCC 15038). Two lots (Lot Nos. CET092304SI004 and CET092304SI005) of the product, PS1B, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. A 1:12 use solution of the product was prepared using 250 ppm AOAC synthetic hard water (titrated at 253 ppm; yielding 2% $H_2O_2$). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 mL of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 25-30°C at 2.7% relative humidity. For each lot of product, separate carriers were sprayed at a distance of 8-12 inches until the carrier surfaces were visibly wet. Each carrier was exposed to the use solution for 5 minutes at 21°C at 4.3% relative humidity. Following exposure, remaining liquid was allowed to drain from the carriers. The carriers were transferred to 20 ml of Letheen Broth with 0.07% Lecithin, 0.5% Tween 80, and 0.05% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 25-30°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported colony forming units per carrier population control is ***Enterobacter aerogenes*** **5.3 x $10^6$**.

**17. MRID 464561-24 "AOAC Germicidal Spray Method, Test Organism: *Listeria monocytogenes* (ATCC 19117)" for PS1B, by Amy Jeske. Study conducted at ATS Labs. Study completion date – December 20, 2004. Project Number A02586.**

This study was conducted against *Listeria monocytogenes* (ATCC 19117). Two lots (Lot Nos. CET092304SI004 and CET092304SI005) of the product, PS1B, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. A 1:12 use solution of the product was prepared using 250 ppm AOAC synthetic hard water (titrated at 248 ppm; yielding 2% $H_2O_2$). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 19.3% relative humidity. For each lot of product, separate carriers were sprayed at a distance of 8-12 inches until the carrier surfaces were visibly wet. Each carrier was exposed to the use solution for 5 minutes at 19.5°C at 10.2% relative humidity. Following exposure, remaining liquid was allowed to drain from the carriers. The carriers were transferred to 20 ml of Letheen Broth with 0.07% Lecithin, 0.5% Tween 80, and 0.05% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported colony forming units per carrier population control is ***Listeria monocytogenes*** **1.12 x $10^5$**.

**18. MRID 464561-25 "Fungicidal Germicidal Spray Method, Test Organism: *Candida albicans* (ATCC 10231)" for PS1B, by Amy Jeske. Study conducted at ATS Labs. Study completion date – December 27, 2004. Project Number A02583.**

This study was conducted against *Candida albicans* (ATCC 10231). Two lots (Lot Nos. CET092304SI004 and CET092304SI005) of the product, PS1B, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. A 1:48 use solution of the product was prepared using 250 ppm AOAC synthetic hard water (titrated at 248 ppm; yielding 0.5% $H_2O_2$). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 2-3 day old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 14.6% relative humidity. For each lot of product, separate carriers were sprayed at a distance of 8-12 inches until the carrier surfaces were visibly wet. Each carrier was exposed to the use solution for 10 minutes at 19.0°C. Following exposure, remaining liquid was allowed to drain from the carriers. The carriers were transferred to 20 ml of Sabouraud Dextrose Broth with 0.07% Lecithin, 0.5% Tween 80, and 0.05% Catalase to neutralize. After 30 minutes, the carriers were transferred to secondary subculture tubes of 20 ml of Sabouraud Dextrose Broth with 0.07% Lecithin, 0.5% Tween 80, and 0.05% Catalase. All subcultures were incubated for 10 days at 25-30°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported colony forming units per carrier population control is ***Candida albicans* 8.3 x $10^5$**.

**19. MRID 464561-26 "AOAC Germicidal Spray Method, Test Organism: *Vibrio cholerae* (ATCC 11623)" for PS1B, by Amy Jeske. Study conducted at ATS Labs. Study completion date – January 17, 2005. Project Number A02587.**

This study was conducted against *Vibrio cholerae* (ATCC 11623). Two lots (Lot Nos. CET092304SI004 and CET092304SI005) of the product, PS1B, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. A 1:12 use solution of the product was prepared using 250 ppm AOAC synthetic hard water (titrated at 249 ppm; yielding 2% $H_2O_2$). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 3-day old suspension of the test organism. The carriers were dried for 30-40 minutes at 25-27°C at 65-67% relative humidity. For each lot of product, separate carriers were sprayed at a distance of 8-12 inches until the carrier surfaces were visibly wet. Each carrier was exposed to the use solution for 5 minutes at 22°C at 26.3% relative humidity. Following exposure, remaining liquid was allowed to drain from the carriers. The carriers were transferred to 20 ml of Letheen Broth with 0.07% Lecithin, 0.5% Tween 80, and 0.05% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, stored at 2-8°C for 2 days, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported colony forming units per carrier population control is ***Vibrio cholerae* 3.1 x $10^4$**.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: The applicant provided the data for a failed trial set up on December 13, 2004. In that trial, no growth was observed in the carrier population control. The viability control also failed to show growth. Thus, the test was invalid. These data were not used to evaluate efficacy of the test product. See Attachment I of the laboratory report.

## V. RESULTS

| MRID Number | Organism | Lot No. | Carrier Type | No. Exhibiting Growth/No. Tested |
|---|---|---|---|---|
| 464561-15 | *Bacillus subtilis* | Lot No. CET092304SI004 | sutures<br>penicylinders | 1° 0/60; 2° 0/60<br>1° 0/60; 2° 0/60 |
| | *Clostridium sporogenes* | Lot No. CET092304SI004 | sutures<br>penicylinders | 1° 0/60; 2° 0/60<br>1° 0/60; 2° 0/60 |
| | *Bacillus subtilis* | Lot No. CET092304SI005 | sutures<br>penicylinders | 1° 0/60; 2° 0/60<br>1° 0/60; 2° 0/60 |
| | *Clostridium sporogenes* | Lot No. CET092304SI005 | sutures<br>penicylinders | 1° 0/60; 2° 0/60<br>1° 0/60; 2° 0/60 |
| | *Bacillus subtilis* | Lot No. CET051904SI002 | sutures<br>penicylinders | 1° 0/60; 2° 0/60<br>1° 0/60; 2° 0/60 |
| | *Clostridium sporogenes* | Lot No. CET051904SI002 | sutures<br>penicylinders | 1° 0/60; 2° 0/60<br>1° 0/60; 2° 0/60 |
| 464561-16 | *Bacillus subtilis* | Lot No. CET092304SI004 | sutures<br>penicylinders | 0/30<br>0/30 |
| | *Clostridium sporogenes* | Lot No. CET092304SI004 | sutures<br>penicylinders | 0/30<br>0/30 |

| MRID Number | Organism | No. Exhibiting Growth/ Total No. Tested | | | Dried Carrier Count (CFU/ carrier) |
|---|---|---|---|---|---|
| | | Lot No. CET051904SI002 | Lot No. CET043004FG008 | Lot No. CET120903FG003 | |
| 464561-08 | *Staphylococcus aureus* | 0/60 | 0/60 | 0/60 | $2.4 \times 10^6$ |
| | *Pseudomonas aeruginosa* | 0/60 | 0/60 | 0/60 | $1.4 \times 10^6$ |
| | *Salmonella choleraesuis* | 0/60 | 0/60 | 1/60 | $3.7 \times 10^5$ |
| 464561-09 | *Staphylococcus aureus* | 0/60 | 0/60 | 0/60 | $6.5 \times 10^4$ |
| | *Pseudomonas aeruginosa* | 0/60 | 0/60 | 0/60 | $2.0 \times 10^5$ |
| | *Salmonella choleraesuis* | | | | |

| MRID Number | Organism | No. Exhibiting Growth/ Total No. Tested | | | Dried Carrier Count (CFU/ carrier) |
|---|---|---|---|---|---|
| | | **Lot No. CET051904SI002** | **Lot No. CET043004FG008** | **Lot No. CET120903FG003** | |
| | | 0/60 | 0/60 | 0/60 | $6.2 \times 10^4$ |
| 464561-11 | *Mycobacterium bovis* BCG Modified Proskauer Beck Medium | 0/10 | 0/10 | — | $1.6 \times 10^5$ |
| | Middlebrook 7H9 Broth | 0/10 | 0/10 | — | |
| | Kirchner Medium | 0/10 | 0/10 | — | |
| 464561-20 | *Trichophyton mentagrophytes* | 0/10 | 0/10 | --- | $2.7 \times 10^4$ |
| | | **Lot No. CET092304SI004** | **Lot No. CET092304SI005** | | |
| 464561-22 | *Salmonella typhimurium* | 0/10 | 0/10 | --- | $8.3 \times 10^4$ |
| 464561-23 | *Enterobacter aerogenes* | 0/10 | 0/10 | --- | $5.3 \times 10^6$ |
| 464561-24 | *Listeria monocytogenes* | 0/10 | 0/10 | --- | $1.12 \times 10^5$ |
| 464561-26 | *Vibrio cholerae* | 0/10 | 0/10 | --- | $3.1 \times 10^4$ |
| 464561-25 | *Candida albicans* | 1° 0/10<br>2° 0/10 | 1° 0/10<br>2° 0/10 | --- | $8.3 \times 10^5$ |

| MRID No. | Organism | Results | | | | Plate Recovery Control |
|---|---|---|---|---|---|---|
| | | | **Lot No. CET051904SI002** | **Lot No. CET043004FG008** | **Lot No. CET051204SI001** | |
| 464561-12 | Influenza virus type A | $10^{-2}$ to $10^{-7}$ dilutions | Complete inactivation | Complete inactivation | Complete inactivation | ($ELD/EID_{50}$/ ml) |
| | | $ELD/EID_{50}$/ml | $\leq 10^{1.5}$ | $\leq 10^{1.5}$ | $\leq 10^{1.5}$ | $10^{6.0}$ |
| | | Log reduction | $\geq 4.5$ $\log_{10}$ | $\geq 4.5$ $\log_{10}$ | $\geq 4.5$ $\log_{10}$ | |
| 464561-19 | Influenza virus type B | $10^{-2}$ to $10^{-7}$ dilutions | Complete inactivation | Complete inactivation | Complete inactivation | ($ELD/EID_{50}$/ ml) |
| | | $ELD/EID_{50}$/ml | $\leq 10^{1.5}$ | $\leq 10^{1.5}$ | $\leq 10^{1.5}$ | $10^{6.0}$ |

| MRID No. | Organism | Results | | | | Plate Recovery Control |
|---|---|---|---|---|---|---|
| | | | Lot No. CET051904 SI002 | Lot No. CET043004 FG008 | Lot No. CET051204 SI001 | |
| | | Log reduction | ≥4.5 $\log_{10}$ | ≥4.5 $\log_{10}$ | ≥4.5 $\log_{10}$ | |
| 464561-21 | Poliovirus type 1 | $10^{-2}$ to $10^{-3}$ dilution | Cyto-toxicity | Cyto-toxicity | Cyto-toxicity | (CCID/ml) $10^{6.0}$ |
| | | $10^{-4}$ to $10^{-7}$ dilutions | Complete inactivation | Complete inactivation | Complete inactivation | |
| | | $CCID_{50}$/ml | $\leq 10^{3.5}$ | $\leq 10^{3.5}$ | $\leq 10^{3.5}$ | |
| | | Log reduction | **≥2.5 $\log_{10}$** | **≥2.5 $\log_{10}$** | **≥2.5 $\log_{10}$** | |

| MRID Number | Organism | Lot No. | Average No. Surviving | Initially Population | Percent Reduction |
|---|---|---|---|---|---|
| | | | (CFU/ml) | | |
| 464561-10 | *Escherichia coli* | CET051204SI001 | <10 | $1.24 \times 10^8$ | >99.999 |
| | | CET070904SI003 | <10 | $1.24 \times 10^8$ | >99.999 |
| | | CET051904SI002 | <10 | $1.24 \times 10^8$ | >99.999 |
| | *Staphylococcus aureus* | CET051204SI001 | <10 | $1.1 \times 10^8$ | >99.999 |
| | | CET070904SI003 | <10 | $1.1 \times 10^8$ | >99.999 |
| | | CET051904SI002 | <10 | $1.1 \times 10^8$ | >99.999 |

| MRID Number | Organism | Results | | | Dried Virus Control ($TCID_{50}$/ 0.1 ml) |
|---|---|---|---|---|---|
| | | | Lot No. CET051904SI002 | Lot No. CET070904SI003 | |
| 464561-13 | Reovirus | $10^{-1}$ to $10^{-10}$ dilutions | Complete inactivation | Complete inactivation | $10^{6.25}$ |
| | | $TCID_{50}$/0.1 ml | $\leq 10^{0.5}$ | $\leq 10^{0.5}$ | |
| | | Log reduction | ≥6.0 $\log_{10}$ | ≥6.0 $\log_{10}$ | |
| 464561-14 | Human | $10^{-1}$ dilution | Cytotoxicity | Cytotoxicity | |
| | | $10^{-2}$ to $10^{-6}$ | Complete | Complete | |

| MRID Number | Organism | Results | | | Dried Virus Control ($TCID_{50}$/ 0.1 ml) |
|---|---|---|---|---|---|
| | | | Lot No. CET051904SI002 | Lot No. CET070904SI003 | |
| | coronavirus | dilutions | inactivation | inactivation | $10^{4.5}$ |
| | | $TCID_{50}$/0.1 ml | $\leq 10^{1.5}$ | $\leq 10^{1.5}$ | |
| | | Log reduction | $\geq 3.0$ $log_{10}$ | $\geq 3.0$ $log_{10}$ | |
| 464561-17 | Hepatitis A virus | $10^{-1}$ to $10^{-8}$ dilutions | Complete inactivation | Complete inactivation | $10^{7.5}$ |
| | | $TCID_{50}$/0.1 ml | $\leq 10^{0.5}$ | $\leq 10^{0.5}$ | |
| | | Log reduction | $\geq 7.0$ $log_{10}$ | $\geq 7.0$ $log_{10}$ | |
| 464561-18 | Avian Influenza A virus | $10^{-1}$ dilution | Cytotoxicity | Complete inactivation | $10^{5.75}$ |
| | | $10^{-2}$ to $10^{-7}$ dilutions | Complete inactivation | Complete inactivation | |
| | | $TCID_{50}$/0.1 ml | $\leq 10^{1.5}$ | $\leq 10^{0.5}$ | |
| | | Log reduction | $\geq 4.25$ $log_{10}$ | $\geq 5.25$ $log_{10}$ | |

## VI. CONCLUSIONS

### A. Conclusions Regarding Use of the Product as a Sterilant

1. The submitted efficacy data (MRID No. 464561-15 and -16) **support** the use of the product, 24% PS1B and CET PS1'B, as a sterilant with sporicidal activity against *Bacillus subtilis* and *Clostridium sporogenes* in the presence of 250 ppm hard water for a contact time of 45 minutes at a 1:6 dilution. During basic testing, no growth was observed in the subcultures of the required number of carriers tested against three lots of the product. During confirmation testing, no growth was observed in the subcultures of the required number of carriers tested against one product lot. Neutralization effectiveness/confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. When reported, purity controls were reported as pure. Sterility controls did not show growth. Test spores showed resistance to acid for $\geq$ 2 minutes, as required.

### B. Conclusions Regarding Use of the Product as a Disinfectant

1. The submitted efficacy data **support** the use of the product, CET PS1'B, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 250 ppm hard water and a 5% organic soil load (heat-inactivated horse serum) for a contact time of 5 minutes at a 1:12 dilution:

*Pseudomonas aeruginosa* MRID Nos. 464561-08 and -09

| | |
|---|---|
| *Salmonella choleraesuis* | MRID Nos. 464561-08 and -09 |
| *Staphylococcus aureus* | MRID Nos. 464561-08 and -09 |

Killing was observed in the subcultures of at least 59 of the 60 carriers tested against three lots of the product. At least one of the product lots tested was at least 60 days old at the time of testing. Dried carrier counts were at least $10^4$. Neutralizer effectiveness testing showed positive growth of the microorganisms. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data **support** the use of the product, PS1B, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 250 ppm hard water and a 5% organic soil load (fetal bovine serum) for a contact time of 5 minutes at a 1:12 dilution:

| | |
|---|---|
| *Enterobacter aerogenes* | MRID No. 464561-23 |
| *Listeria monocytogenes* | MRID No. 464561-24 |
| *Salmonella typhimurium* | MRID No. 464561-22 |
| *Vibrio cholerae* | MRID No. 464561-26 |

Killing was observed in the subcultures of the required number of carriers tested against two lots of the product. Dried carrier counts were at least $10^4$. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

**3. The submitted efficacy data (MRID No. 464561-11) support the use of the product, CET PS1'B, as a disinfectant with tuberculocidal activity against *Mycobacterium bovis* BCG on hard, non-porous surfaces in the presence of 250 ppm hard water and a 5% organic soil load (heat-inactivated horse serum) for a contact time of 10 minutes at a 1:6 dilution. No growth was observed in any of the three recovery media for any of the 10 carriers per two product lots tested. Neutralizer effectiveness testing showed positive growth of the microorganism. Viability controls were positive for growth. Sterility controls did not show growth.**

**4. The submitted efficacy data support the use of the product, CET PS1'B and PS1B, as a disinfectant with fungicidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 250 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1:48 dilution:**

| | |
|---|---|
| ***Candida albicans*** | **MRID No. 464561-25** |
| ***Trichophyton mentagrophytes*** | **MRID No. 464561-20** |

**No growth was observed in the subcultures of the required number of carriers tested against two lots of the product. Neutralizer effectiveness/confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Dried carrier counts for *Trichophyton mentagrophytes* averaged $10^4$, which is consistent with EPA's interim policy. [For more details about this interim policy, see Section III of this efficacy report.] Dried carrier counts for *Candida albicans* were at least $10^5$, which is acceptable.**

5. The submitted efficacy data **support** the use of the products, PS1B, CET PS1B, CET PS1'B and PS1'B, as disinfectants with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 5% organic soil load (fetal bovine serum) at a 1:6 dilution for the

contact times listed:

| | | |
|---|---|---|
| Influenza virus type A | t0 minutes | MRID No. 464561-12 |
| Reovirus | 10 minutes | MRID No. 464561-13 (250 ppm hard water) |
| Human coronavirus | 10 minutes | MRID No. 464561-14 (250 ppm hard water) |
| Avian Influenza A virus | 10 minutes | MRID No. 464561-18 (250 ppm hard water) |
| Influenza virus type B | 10 minutes | MRID No. 464561-19 |

Recoverable virus titers of at least $10^4$ were achieved. Complete inactivation (no growth) was indicated in all dilutions tested except for the studies against Human coronavirus and Avian Influenza A virus, cytotoxicity was observed in the $10^{-1}$ dilution. Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

6. The submitted efficacy data **do not support** the use of the products, PS1B, CET PS1B, CET PS1'B and PS1'B, as disinfectants with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load at a 1:6 dilution:

| | |
|---|---|
| Hepatitis A virus | MRID No. 464561-17 (250 ppm hard water) |
| Poliovirus type 1 | MRID No. 464561-21 |

**The maximum authorized contact time for a disinfectant is 10 minutes.** In the study against Poliovirus type 1, cytotoxicity was observed in the $10^{-2}$ and $10^{-3}$ dilutions; At least a **2.5-log** reduction in titer was demonstrated beyond the cytotoxic level.

**C. Conclusions Regarding Use of the Product as a Sanitizing Rinse on Food Contact Surfaces**

1. The submitted efficacy data (MRID Nos. 464561-10) **support** the use of the product, PS1B, as a sanitizing rinse against *Escherichia coli* and *Staphylococcus aureus* on previously cleaned, hard, non-porous, food contact surfaces at a 1:12 dilution in the presence of 250 ppm hard water and a 5% organic soil load (fetal bovine serum) for a contact time of 30 seconds. At least one of the product lots tested was at least 60 days old at the time of testing. A >99.999% reduction in population within 30 seconds was observed. Number controls were between 75 and 125 x $10^6$/ml. Neutralization confirmation testing met the acceptance criterion of growth within 1.0 $\log_{10}$ of the neutralization confirmation numbers control. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

**VII. RECOMMENDATIONS**

**A. Recommendations Regarding Proposed Sterilant Claims**

1. The proposed label claims that the product, Peridox™, is an effective sterilant against *Bacillus subtilis* and *Clostridium sporogenes* in the presence of 250 ppm hard water and a **5% organic soil** load for a contact time of 45 minutes at a 4% concentration (1:6 dilution); are **not acceptable by the Agency for practicability issues**. Not all, non-porous, sprayed surface can stay wet for 45 minutes. The applicant may provide the results of efficacy testing conducted in very short contact time (5 to 10 minutes for examples).

**B. Recommendations Regarding Proposed Disinfectant Claims**

1. The proposed label claims that the product, Peridox™, is an effective virucidal against Hepatitis A virus and Poliovirus (Sabin) for a contact time of 30 minutes, **are not acceptable by the Agency**. The maximum authorized contact time for a disinfectant is 10 minutes. **The applicant must remove Hepatitis A and Poliovirus (Sabin) claims from the label.**

2. In the effort to suppress multiple contact times and dilutions for disinfection uses of a product, the Agency adopted "**one dilution, one contact time**" approach for efficacy reasons. By consequent the product Perodox™ can only be used at one dilution (**51oz. per 2 gallons or 4%** $H_2O_2$) and one contact time (**10 minutes**) for disinfection/cleaning purposes.

3. The proposed label claims that the product, Peridox™, is an effective disinfectant on hard, non-porous surfaces against the following microorganisms in the presence of 250 ppm hard water and a 5% organic soil load at the dilutions and contact times listed:

| | | |
|---|---|---|
| *Pseudomonas aeruginosa* | 2% $H_2O_2$; 1:12 dilution | 5 minutes |
| *Salmonella choleraesuis* | 2% $H_2O_2$; 1:12 dilution | 5 minutes |
| *Staphylococcus aureus* | 2% $H_2O_2$; 1:12 dilution | 5 minutes |
| *Enterobacter aerogenes* | 2% $H_2O_2$; 1:12 dilution | 5 minutes |
| *Listeria monocytogenes* | 2% $H_2O_2$; 1:12 dilution | 5 minutes |
| *Salmonella typhimurium* | 2% $H_2O_2$; 1:12 dilution | 5 minutes |

**These claims are not acceptable by the Agency**. The applicant should add *Vibrio cholerae* to the list of bacteria under the "Combination Disinfection and Cleaning" directions. At a 4% $H_2O_2$ concentration in 250 ppm hard water and a 5% organic soil load, the product is effective against *Vibrio cholerae* at a contact time of 10 minutes. **The Agency recommends 4% $H_2O_2$ or 1:6 dilution and 10 minutes contact time for the following microorganisms**:

| | |
|---|---|
| *Pseudomonas aeruginosa* | *Salmonella choleraesuis* |
| *Staphylococcus aureus* | *Enterobacter aerogenes* |
| *Listeria monocytogenes* | *Salmonella typhimurium* |
| *Mycobacterium bovis* BCG | *Vibrio cholerae* |
| *Candida albicans* | *Trichophyton mentagrophytes* |

4. The proposed label claims that the product, Peridox™, is an effective fungicidal on hard, non-porous surfaces against *Candida albicans* and *Trichophyton mentagrophytes* in the presence of 250 ppm hard water, a 5% organic soil load, and soap scum for a contact time of 10 minutes at a 0.5% concentration (1:48 dilution) **are not acceptable by the Agency**. Testing was not conducted in the presence of soap residue. For this reason, **the applicant must delete from the proposed label the supplemental claim of efficacy in the presence of soap scum** (or provide the results of efficacy testing conducted in the presence of soap scum (e.g., 0.005% sodium stearate)).The applicant should revise the fungicidal directions by adding a statement to pre-clean heavily soiled areas. The applicant should revise the fungicidal directions by adding a statement regarding how (or whether) to remove the product from treated surfaces, for example, "Remove solution and entrapped soil with a clean cloth."

5. The proposed label includes directions for using the product to disinfect pharmaceutical and cosmetic surfaces. For this application, the proposed label claims that the product, Peridox™, is effective in the presence of dried soap film residue. The applicant **has not provided** efficacy data

developed in the presence of soap residue. For this reason, **the applicant must delete from the proposed label the supplemental claim of efficacy in the presence of dried soap film residue** (or provide the results of efficacy testing conducted in the presence of soap residue (e.g., 0.005% sodium stearate)).

6. The proposed label claims that the product, Peridox™, is an effective virucidal on hard, non-porous surfaces against **Human coronavirus**, **Influenza A** (H10N7) virus (i.e., **Avian Influenza A virus**), and **Reovirus**, in the presence of 250 ppm hard water and a 5% organic soil load at a 4% concentration (1:6 dilution) for 10 minutes contact time; **are supported by the Applicant data**. The applicant should revise the virucidal directions by adding a statement to pre-clean heavily soiled areas. The applicant should revise the virucidal directions by adding a statement regarding how (or whether) to remove the product from treated surfaces, for example, "Remove solution and entrapped soil with a clean cloth."

Please Note: Acceptance of the data to support a label claim for the Human coronavirus does not in any way support a label claim for the product as an effective disinfectant against the causative agent of Severe Acute Respiratory Syndrome (SARS).

7. The proposed label claims that the product, Peridox, is an effective disinfectant on hard, non-porous surfaces against **Influenza A (H3N2)** virus and **Influenza B virus** in the presence of 250 ppm hard water and a 5% organic soil load at a 4% concentration (1:6 dilution) for 10 minutes contact time; **are not fully supported by the applicant data**. Testing **was not conducted** in the presence of 250 ppm hard water. For this reason, **the applicant needs to delete from the proposed label the supplemental claim of efficacy in the presence of 250 ppm hard water** (or provide the results of efficacy testing conducted in the presence of 250 ppm hard water). The applicant should revise the virucidal directions by adding a statement to pre-clean heavily soiled areas. The applicant should revise the virucidal directions by adding a statement regarding how (or whether) to remove the product from treated surfaces, for example, "Remove solution and entrapped soil with a clean cloth."

8. The proposed label claims that the product, Peridox™, is an effective disinfectant on hard, non-porous surfaces against Influenza A (H1N2) virus. The applicant **did not provide data** to support this claim. **The applicant must delete all references to Influenza A (H1N2) virus from the proposed label.**

**C. Recommendations Regarding Proposed Sanitizing Rinse Claims**

1. The proposed label claims that the product, Peridox™, is an effective sanitizing rinse for use on pre-cleaned surfaces at a 2% concentration in the presence of 250 ppm hard water. Data provided by the applicant **support** these claims. **The applicant must revise the sanitization directions to state that a contact time of at least 1 minute is required** (DIS/TSS-4) **in order to keep food contact sanitizer rinse claims.** The applicant should expand the sanitization directions to include language such as "Pre-clean surfaces to remove gross particles. Wash with a detergent solution. Rinse with potable water." The applicant should revise the sanitization directions by adding a statement on how the use solution should be applied, and by adding a statement regarding how (or whether) to remove the product from treated surfaces.

**D. Recommendations Regarding Proposed Non-Food Sanitizer Claims**

1. The proposed label claims that the product, Peridox™, is an effective sanitizer on non-food contact surfaces against the following microorganisms at a 2% concentration in the presence of 250 ppm hard water: *Staphylococcus aureus*, *Enterobacter aerogenes*, *Escherichia coli*, *Listeria monocytogenes*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa*. The applicant **did not provide** data meeting Agency testing requirements and standards in DIS/TSS-10. **The applicant must delete all references to use of the product as a sanitizer on non-food contact surfaces.** Note: The applicant did provide data supporting use of the product as a disinfectant against each of these microorganisms (except for *Escherichia coli*).

**E. Miscellaneous Recommendations**

1. The proposed label [see page 2 of the proposed label] claims that the product is effective against "*Streptococcus thermophilus.*" The applicant **did not provide data** to support this claim. **The applicant must delete all references to *Streptococcus thermophilus* from the proposed label.**

2. The instructions for using the product with the Electrostatic Decontamination System describe treatment efficiency using the words "decontaminate," "disinfect," and "sterilize." The efficacy data provided by the applicant did not include use of the UV light wand after application of the product; therefore, **the applicant must delete the section "Use With Electrostatic Decontamination System"**

3. The instructions for "Use Without Electrostatic Decontamination System" [see page 4 of the proposed label" are confusing. **Information in the last two sentences of these instructions is inconsistent with information previously presented.** For example, the instructions state that the product should "remain on the surface the indicated contact time;" however, the second to last sentence states that the product should "remain on surface for 10 minutes before evaporation." For example, the instructions state that treated surfaces should be wiped with a clean cloth after the contact period; however, the last sentence states that treated surfaces should air dry.

4. In the Virucidal directions (in 2 places) [see page 5 of the proposed label], the applicant should change "organic soil" to read "a **5%** organic load." Testing was conducted in the presence of a 5% organic soil, and the directions should reflect this.
5. Currently, directions for using the product against *Mycobacterium bovis* are included in the "Virucidal" directions [see page 6 of the proposed label.] The applicant should add a new section entitled "**Tuberculocidal**" directions to the proposed label, and place the directions regarding *Mycobacterium bovis* in this new section. The applicant should also change "organic soil" to read "a **5%** organic load."

6. The applicant should make the following changes, as appropriate:

- On page 1, correct the spelling of the word "**emergency**" in "FOR E**MBERGENCY** MEDICAL INFORMATION."

- On page 2, correct the spelling of "*Es**cher**icher**ia coli*" to read "*Es**cher**ich**ia coli.*"

- On page 2, correct the spelling of "*Sa**lmonaella** typhimurium*" to read "*Sa**lmonell**a typhimurium.*"

- On page 2, correct the spelling of "*Ca**ndid**a a**tbacans***" to read "*Candida a**lbicans.***"