UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 19, 2007

MEMORANDUM

Subject: Efficacy Review for Peridox™, EPA File Symbol 81073-1; DP Barcode: D335446

From: Ibrahim Laniyan, Microbiologist
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To: Marshall Swindell / Karen Leavy
Regulatory Management Branch I
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Applicant: Clean Earth Technologies, LLC
13378 Lakefront Drive
St. Louis, MO 63045

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 81073-1), is a new product. The applicant requested to register the product as a sterilant, disinfectant (bactericide, virucide, tuberculocide, fungicide), sanitizer for non-food contact surfaces, and sanitizing rinse for previously cleaned, food contact surfaces. The applicant requested an amendment to the registration of this product to add mold claims. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121; and Clean Earth Technologies, LLC, located at 13378 Lakefront Drive, Earth City, MO 63045.

This data package contained letters from the applicant's representative to EPA (dated December 13, 2006), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-35 (Data Matrix), three studies (MRID Nos. 470075-01, 471064-01, and 471064-02), Statements of No Data Confidentiality Claims for all three studies, and the proposed label.

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 1 gallons of water (a 1:6 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. Remove solution and entrapped soil with a dry clean cloth.

Virucidal disinfectant or as a disinfectant against *Mycobacterium bovis*: Prepare a use solution by adding 26 ounces of the product to 1 gallons of water (1:6 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. Remove solution and entrapped soil with a dry clean cloth.

Fungicidal disinfectant: Prepare a use solution by adding 26 ounces of the product to 1 gallons of water (1:6 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. Remove solution and entrapped soil with a dry clean cloth.

Mold and mildew control: Where possible visible mold and mildew growth should be removed from surface prior to treatment. Prepare a dilute solution by adding 5 parts

water to 1 part 24% PERIDOX™. Apply the use solution using a spray applicator device or soak to wet all surfaces thoroughly. Allow surfaces to remain wet for 10 minutes. Remove solution and entrapped soil with a dry clean cloth.

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 12 ounces of the product to 1 gallons of water (1:10.67 dilution; a 2% H_2O_2 concentration). Allow surfaces to remain wet for one minute. Rinse with potable water.

The proposed label directions also included special instructions for cleaning and decontaminating against HIV-1 on pre-cleaned surfaces or objects previously soiled with blood/body fluids. Finally, the label directions noted that: "This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument . . . ."

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Products for control of mold and mildew on surfaces (Mildewcides / Fungicides): The efficacy of products that claim to kill mildew is dependent upon concentration and length of time the active ingredient is in contact with the organism. Methods for testing such products are "Glass Slide Mildew Fungicidal Test Method" and "Use-Dilution Mildew Fungicidal Test Method". The test method should be modified for surfaces other than hard, nonporous surfaces.

Mildewcides should also be tested to determine whether or not bleaching, staining, spotting or other undesirable effects occur on the surfaces, articles, and materials to be protected.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 470075-01 "Fungicidal Germicidal Spray Method" for Peridox™, by Anne Stemper; Project number: A04475. Study conducted at ATS Labs. Study completed on December 4, 2006.

This study was conducted against *Aspergillus niger* (ATCC 16404). Two lots (Lot Nos. CET052306S1023 and CET101806S1028) of the product, Peridox™, were tested according to ATS Labs Protocol No. CTL01101306.FGS (copy not provided). The lot CET052306S1023 was at least 60 days old at the time of testing. A 4% use dilution was prepared by adding 1.0 ml of the product to 5.0 ml of 250 ppm AOAC synthetic hard water (titrated at 255 ppm). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 0.01 mL of a conidial suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% humidity. For each lot of product, carriers were sprayed with the product at a distance of 6-8 inches from the carrier surface. Each carrier remained exposed to the product for 10 minutes at room temperature (22.1°C) at 25.0% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Sabouraud Dextrose Broth with 0.07% Lecithin, 0.5% Tween 80 and 0.05% Catalase to neutralize. The carriers were transferred to secondary subcultures of 20 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 at least 30 minutes after

the first transfer. All subcultures were incubated for 10 days at 25-30°C, and agar plate subcultures, 44-76 hours at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average reported initial colony forming units per carrier, for the test microorganism, is: ***Aspergillus niger*** **5.3 x 10^5**.

2. MRID 471064-01 "Fungicidal Spray Test Method on Porous Materials" for Peridox™, by Wanwen Su, Zhijang Pan, and Glen Warren. Study conducted at Clean Earth Technologies, LLC. Study completed on March 28, 2007.

This study was conducted against *Aspergillus niger* (ATCC 16404). The method principle is described as follows: Spores of *Aspergillus niger* (prepared according to the standard procedure or purchased from Presque Isle Cultures) with 5% organic load were applied to coupon surfaces of different porous materials. These coupons were put into a Petri dish or 6-well plates and dried under vacuum for 60 minutes. After drying, PERIDOX™ was sprayed onto the material surfaces until all surfaces were wet. The coupon surfaces were kept wet for 10 minutes, and then neutralized *in situ*. The neutralized coupons along with the remaining solution inside the container were transferred to a 50 ml Falcon tube containing wash buffer. The Falcon tube was vortexed for 1 minute to recover the spores from the coupons. This recovery solution was serially diluted, and the entire volume of each dilution was filtered through the filter using a vacuum pump. The filter was then incubated on Sabouraud agar at 25°C and relative humidity > 50% for 7 days. The plates were then counted for colonies and results were calculated for log reduction in comparison to spore recovery from the controls. The detailed step-by-step procedure is provided in the protocol (SOP 0117) submitted with this report.

With the developed method described above (FSTM-PM), Clean Earth Technologies (CET) tested different porous materials using coupons of construction materials including carpet, wood, painted drywall, and polyester fabric. These coupons were cut into circles of 22 mm in diameter and sterilized. The coupons were inoculated with 1 x 10^6 to 1.6 x 10^6 spores of *Aspergillus niger*. Each coupon was sprayed with PERIDOX™ until the whole surface was totally wet. After 10 minutes contact time, the coupons were neutralized, collected, and processed as described above and in the attached protocol.

3. MRID 471064-01 "Visual Reappearance of Mold in a Home Shower Following Treatment with Peridox™", byHeather Woelich. Study conducted at Clean Earth Technologies, LLC. Study completed on March 30, 2007.

This study was conducted against *Aspergillus niger* (purchased from Presque Isle Cultures). The study was performed to determine the time interval for the visual reappearance of mold growth following treatment with of the painted drywall ceiling in a bathroom containing a home shower stall. The study comprised the periodic treatment of the ceiling and periodic post-treatment visual inspection for the reappearance of mold growth. As staining of the painted drywall progressively worsened with successive test cycles, the criterion for reappearance is the visual reappearance in comparison with the post-treatment condition for that test cycle.

Note that the descriptive approach of this study made it unusable to support residual activity of 4% Peridox™ over four weeks period.

V. RESULTS

MRID # 470075-01	Lot #	Sample Dilution	Contact Time	No. Exhibiting Growth/Total No. Tested	Dried Carrier Count (CFU/carrier)
Aspergillus niger	CET052306S1023	4%	10 minutes	1°= 0/10 2°= 0/10	5.3 x $t0^5$
	CET101806S1028			1°= 0/10 2°= 0/10	

MRID # 471064-01	Materials	Sample Dilution	Contact Time	Results	Controls
Aspergillus niger.	Carpet	4%	10 minutes	5.52 logs kill	4.72 logs to 5.62 logs
	Wood			No survivor detected	
	Painted Drywall			No survivor detected	
	Polyester Fabric			No survivor detected	

VI. CONCLUSIONS

1. The submitted efficacy data (MRID 470075-01) **support** the use of 4% of the product, Peridox™, as a disinfectant with fungicidal activity against *Aspergillus niger* on hard, non-porous surfaces in the presence of a 5% organic soil load (fetal bovine serum) for a contact time of 10 minutes at room temperature.

2. The submitted efficacy data (MRID 471064-01) **support** the use of 4% of the product, Peridox™, as a disinfectant with fungicidal activity against *Aspergillus niger* on porous surfaces in the presence of a 5% organic soil load (fetal bovine serum) for a contact time of 10 minutes at room temperature. **Carpet type must be specified.**

3. The submitted efficacy data (MRID 471064-02) **did not support** the use of 4% of the product, Peridox™, as a fungicidal with over 4 weeks residual activity against *Aspergillus niger.* **The descriptive approach of this study made it unusable to support residual activity of 4% Peridox™ over four weeks period**

VII. RECOMMENDATIONS

1. The proposed label claims that the product, Peridox™, is an effective fungicidal against *Aspergillus niger* (mold) on **porous** and **hard non-porous surfaces**, when used at 4% for a contact time of 10 minutes, **are supported** by the applicant's data.

2. The proposed label claims that the product, Peridox™, has over 4 weeks fungicidal residual effect against *Aspergillus niger* (mold) when used at 4% for a contact time of 10

minutes, **are not supported** by the applicant's data. **The applicant must remove all over 4 weeks fungicidal residual claims.**

3. **Applicant must specify type of carpet or remove carpet claims.**

4. The specie name of *Salmonella choleraesuis* has been changed by ATCC. The new designation of this organism is *Salmonella* ***enterica***. This change is effective immediately, and should be used for all subsequent references to this organism in the future.