

81073-1

12/15/2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 15 2005

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Erin Tesch
Consultant for,
Clean Earth Technologies, Inc.
13378 Lakefront Drive
Earth City, Mo 63045

Mail to: Attn: Erin Tesch
Technology Sciences Group, Inc.
1101 17th Street, N.W.
Washington, D.C. 20036

Subject: Peridox [™]
EPA Registration Number 81073-1
Your Notification Dated November 17th, 2005
EPA Received Date November 17th, 2005

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to revise the product labeling to list and group the organisms together as per request of California Department of Pesticide Regulation, is acceptable.

Your notification has been made part of the permanent records for this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703) 308-6237.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell".

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division (7510C)

2/10



WASHINGTON

1101 17th Street, N.W.

Suite 500

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Mr. Marshall Swindell
Office of Pesticide Program
Antimicrobial Division (AD)
Environmental Protection Agency (EPA)
1801 South Bell Street
Arlington, VA 22202-4501

November 17, 2005

SUBJECT: PERIDOX™ (EPA File Symbol 81073-1)
Label Notification to reformat list or organisms per PR Notice
98-10

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

Dear Mr. Swindell:

Technology Sciences Group, on behalf of Clean Earth Technologies, LLC submits the enclosed notification to reformat the listing or organisms on the label as previously approved by EPA. This reformatting was requested by the California Department of Pesticide Regulation in their concurrent review of the PERIDOX™ application. It is important to note that no organisms have been added or deleted to the enclosed label but simply reformatted.

You will find the following to support this notification:

- 1) Application form (EPA 8570-1);
- 2) One redline copy of the label (changes highlight in red font); and
- 3) Three clean copies of the revised label.

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

If you have any questions, please feel free to contact me at (202) 828-8966 or Etesch@tsgusa.com.

Sincerely,

Erin M. Tesch
Regulatory Agent for Clean Earth Technologies, LLC

Enclosures

cc: Dr. Jeff Golden, Clean Earth Technologies, LLC
Dr. Joan Stader, Clean Earth Technologies, LLC

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Clean Earth Technologies 81073-1	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Periodox	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Clean Earth Technologies, LLC 13378 Lakefront Drive Earth city, MO 63045 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is a notification to reformat list of previously approved organisms on the label per PR Notice 98-10 and is not subject to PRIA. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling of the Confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. 1L or 2L	No. per container 4 or 8	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 or 2 L		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Erin M. Tesch, Technology Sciences Group, Inc.		Title Consultant to Clean Earth Technologies		Telephone No. (Include Area Code) 202-828-8965	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Consultant to Clean Earth Technologies, LLC			
4. Typed Name Erin M. Tesch		5. Date 11/17/05			

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MASTER LABEL
PERIDOX™

ACTIVE INGREDIENTS:

Hydrogen Peroxide.....	24.0%
Peroxyacetic Acid.....	1.2%
Other Ingredients.....	74.8%
Total.....	100.0%

KEEP OUT OF REACH OF CHILDREN
DANGER PELIGRO

FIRST AID	
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Call a poison control center or physician for treatment advice.
IF SWALLOWED	Call a poison control center or physician for advice immediately after swallowing. Have a person sip glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or physician. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or physician for treatment advice.
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or physician for further treatment advice.
Have the product container with you when calling a poison control center or going for treatment.	
FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222	
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	

Manufactured by: Clean Earth Technologies, LLC
13378 Lakefront Drive
St. Louis, MO 63045
USA

EPA Reg. No. 81073-1
EPA Est. No.

Net Contents:

[CLAIMS]

For Professional Use

For biological decontamination of hard and nonporous surfaces

For biological disinfection of hard and nonporous surfaces

For sanitizing rinse on previously cleaned nonporous food contact surfaces

[ADDITIONAL CLAIMS]

Sterilant for Aseptic Manufacturing and Packaging Equipment

Disinfectant for the Pharmaceutical and Cosmetic Industry

Sterilant/Disinfectant for Non-patient Contact for Healthcare and Veterinary Facilities

Delivers antimicrobial activity on yeast, molds and bacteria.

Effective against a wide range of viruses, bacteria and fungi, including:

STERILANT	DISINFECTANT	SANITIZER
<i>Bacillus subtilis</i>	Bactericidal:	<i>Escherichia coli</i>
<i>Clostridium sporogenes</i>	<i>Enterobacter aerogenes</i>	<i>Staphylococcus aureus</i>
	<i>Escherichia coli</i>	
	<i>Listeria monocytogenes</i>	
	<i>Pseudomonas aeruginosa</i>	
	<i>Salmonella typhimurium</i>	
	<i>Staphylococcus aureus</i>	
	<i>Vibrio cholerae</i>	
	<i>Salmonella choleraesuis</i>	
	Tuberculocidal:	
	<i>Mycobacterium bovis</i>	
	Viricidal:	
	Avian Influenza A (H3N2)	
	Reovirus	
	Human Coronavirus	
	Fungicidal:	
	<i>Trichophyton</i>	
	<i>mentagrophytes</i>	
	<i>Candida albicans</i>	

Disinfectant: Hospitals, Nursing Homes, Health Care Facilities, Schools, Colleges, Veterinary Clinics, Animal Life Science Laboratories, Industrial Facilities, Dietary Areas, Office Buildings, Recreational Facilities, Retail and Wholesale Establishments, Animal Care Facilities, Veterinary Facilities, Farms, Livestock Quarters, Poultry Premises, Poultry Hatcheries, and vehicles including ships, planes, automobiles, trucks, trains, and EMS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if absorbed through the skin or inhaled. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses), clothing, and chemical resistant gloves. Wash with soap and water thoroughly after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse. Dilute the concentrated PERIDOX™ to the appropriate use rate in a well ventilated area or have available proper respiratory protection.

PHYSICAL AND CHEMICAL HAZARDS: Strong Oxidizing Agent. Corrosive. Do not use in concentrated form. Mix only with water according to label instructions. Never bring concentrate in contact with other sanitizers, cleaners or organic substances.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to birds, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office at the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Before using this product read the entire label.

To apply the PERIDOX™ solution to non-food, non-porous surfaces the measured amount of PERIDOX™, per the Directions for Use, is added to a spray applicator or mixing container and diluted with the measured amount of water, up to 250 ppm hardness as CaCO₃. The "Use Dilutions" for PERIDOX™ are based on the 24.0% hydrogen

peroxide active ingredient. The mixed PERIDOX™ solution is applied to the contaminated surface with a spray applicator device or by soaking the contaminated surface and permitted to remain on the surface the indicated contact time. Spray or soak the surface with a sufficient amount of PERIDOX™ solution to remain on surface for the indicated contact time before evaporation. Air dry or remove with a dry clean cloth or wipe.

[THIS SECTION IS FOR GENERAL USE]

DISINFECTION

Use in Hospitals, Surgical and Obstetrical Suites, Housekeeping Services, Physical Therapy Departments, Nursing Services and Autopsy Facilities.

Use PERIDOX™ in nursing homes, health-care facilities, schools, colleges, veterinary clinics, animal life science laboratories, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments.

Use PERIDOX™ in transport vehicles including ships, planes, automobiles, trucks, trains, and EMS.

Not for use on food contact surfaces, medical devices or medical equipment surfaces.

Combination Disinfection and Cleaning.

PERIDOX™ is effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Enterobacter aerogenes*, *Salmonella typhimurium*, *Listeria monocytogenes*, *Vibrio cholerae*, and *Pseudomonas aeruginosa* at 4% (26 oz PERIDOX™/gallon water) in hard water (250 ppm as CaCO₃) and a 5% organic load on hard nonporous surfaces. For heavily soiled areas a precleaning step is required. Apply PERIDOX™ solution with spray applicator device or soak to wet all surfaces thoroughly. Allow surfaces to remain wet for 10 minutes; then, remove solution and entrapped soil with a dry clean cloth. Prepare a fresh solution daily or, if necessary, more frequently if it becomes soiled or diluted.

Virucidal. PERIDOX™ is effective against Avian Influenza A (H3N2), Reovirus, and Human Coronavirus on hard nonporous inanimate surfaces when used at 4% (26 oz PERIDOX™/gallon water) in hard water (250 ppm CaCO₃) with a 10 minute contact time in the presence of a 5% organic load. For heavily soiled areas a precleaning step is required. Apply PERIDOX™ solution with spray applicator device or soak to wet all surfaces thoroughly. Allow surfaces to remain wet for 10 minutes; then, remove solution and entrapped soil with a dry, clean cloth. Prepare a fresh solution daily or, if necessary, more frequently if it becomes soiled or diluted.

Fungicidal. PERIDOX™ can be used on hard nonporous inanimate surfaces such as shower room floors, shower stalls, locker room benches, and bath mats. At 4% (26 oz PERIDOX™/gallon water), this product is effective against *Trichophyton mentagrophytes* (Athletes Foot Fungi) and *Candida albicans* (pathogenic yeast) in the presence of a 5% organic load in hard water (250 ppm CaCO₃) with a 10 minute contact time. For heavily soiled areas a precleaning step is required. Apply PERIDOX™ solution with spray applicator device or soak to wet all surfaces thoroughly. Allow surfaces to remain wet for 10 minutes; then, remove solution and entrapped soil with a dry, clean cloth. Prepare a fresh solution daily or, if necessary, more frequently if it becomes soiled or diluted.

Tuberculocidal. PERIDOX™ is also effective against *Mycobacterium bovis* on hard nonporous inanimate surfaces when used at 4% (26 oz PERIDOX™/gallon water) with a 10 minute contact time in the presence of hard water (250 ppm CaCO₃) and a 5% organic load. For heavily soiled areas a precleaning step is required. Apply PERIDOX™ solution with spray applicator device or soak to wet all surfaces thoroughly. Allow surfaces to remain wet for 10 minutes; then, remove solution and entrapped soil with a dry clean cloth. Prepare a fresh solution daily or, if necessary, more frequently if it becomes soiled or diluted.

Disinfection of Pharmaceutical and Cosmetic Surfaces. PERIDOX™ is recommended for use on hard, non-porous, environmental surfaces such as floors, walls and processing equipment in pharmaceutical and cosmetic processing facilities. It is effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Enterobacter aerogenes*, *Salmonella typhimurium*, *Listeria monocytogenes*, *Vibrio cholerae*, and *Pseudomonas aeruginosa* at 4% (26 oz PERIDOX™/gallon water) in hard water (250 ppm CaCO₃), and 5% blood serum. For heavily soiled areas a precleaning step is required. Apply PERIDOX™ solution with spray applicator device or soak to wet all surfaces thoroughly with a contact time of 10 minutes. Rinse with sterile water. Remove solution and entrapped soil with a dry, clean cloth. Air dry. Prepare a fresh solution daily or, if necessary, more frequently if it becomes soiled or diluted.

ANTIMICROBIAL TREATMENT

Sterilization of Manufacturing, Filling and Packaging Equipment in Aseptic Processes. Prior to use of PERIDOX™ as a sporicide, remove gross soil particles from processing surfaces, then wash with a detergent solution, followed by a potable water rinse. Prepare a 4% sterilizing solution of PERIDOX™. Apply PERIDOX™ solution by immersion of objects in containers, fill to cover interior surfaces of containers, to wet thoroughly all surfaces with a contact time of 45 minutes. This product is effective against *Clostridium sporogenes* and *Bacillus subtilis* vegetative cells and spores at 4% (26 oz PERIDOX™/gallon water) in hard water (250 ppm CaCO₃) and a 5% organic load. Thoroughly rinse treated surfaces with sterile water. Remove solution and entrapped soil with a dry, clean, sterile cloth. **This product is not for use as a sterilant on medical devices.**

Sterilant for Non-patient Contact Surfaces for Healthcare and Veterinary Facilities.

Prior to use of PERIDOX™ as a sporicide, remove gross soil particles from processing surfaces, then wash with a detergent solution, followed by a potable water rinse. PERIDOX™ is recommended for use as a sterilant on hard, non-porous, inanimate rimmed surfaces that permit flooding, immersible objects in containers and interior surfaces of containers for non-patient contact in healthcare and veterinary facilities. Prepare a 4% (26oz/gallon water) sterilizing solution of PERIDOX™. Apply PERIDOX™ solution by immersion of objects in containers, by covering interior surfaces of containers, or by flooding rimmed surfaces that permit flooding (e.g., floors, tables, counters) to wet thoroughly all surfaces with a contact time of 45 minutes. This product is effective against *Clostridium sporogenes* and *Bacillus subtilis* vegetative cells and spores at 4% (26 oz PERIDOX™/gallon water) in hard water (250 ppm CaCO₃) and a 5% organic load. Remove solution and entrapped soil with a clean, dry, sterile cloth. **This product is not for use as a sterilant on medical devices.**

SANITIZATION**Sanitization Rinse on Pre-cleaned Non-porous Food Contact Surfaces.**

PERIDOX™ is recommended for use on pre-cleaned non-porous, food contact surfaces such as equipment, pipelines, tanks, vats, fillers, and evaporators as a sanitizer rinse. Pre-clean surfaces to remove gross particles. Wash with a detergent solution. Rinse with potable water. Apply PERIDOX™ solution with spray applicator device or soak to wet all surfaces thoroughly. At 2% (12 oz PERIDOX™/gallon water), this product is effective as a sanitizer rinse in hard water (250 ppm as CaCO₃) and a 5% organic load with a contact time of 1 minute. Rinse with potable water after treatment. Remove excess water with a clean dry cloth or allow surfaces to air dry. For manual operations, fresh sanitizing solutions should be prepared daily or more often if the solution becomes diluted or soiled.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in original containers in a cool, well-vented area, away from direct sunlight. Do not allow product to become overheated in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. If material has spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards and other requirements.

CONTAINER DISPOSAL:

(1 gal plastic) Do not reuse empty containers. Wrap container and put in trash.

(15, 30, 60 gal plastic) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY

This material is safe and effective under the conditions of application as specified in the Directions for Use. To the fullest extent permitted by law, the manufacturer shall not be liable for improper application or use of this product beyond those purposes referred to in the Directions for Use. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.