

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

06/06/07

DP BARCODE: D332582

MRID: 464561-01, 464561-02, 466320-01, & 465455-01.

SUBJECT: PeridoxTM with the Electrostatic Decontamination System (EDS) as an Antimicrobial for Sterilization and Decontamination of Bacillus anthracis Spores on Non-porous and Porous Surfaces

REG. NO. OR FILE SYMBOL: 81073-E

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use ☐ OR End-use Product ☒

INGREDIENTS (PC Codes) Hydrogen Peroxide (000595); Peroxyacetic Acid (063201)

CAS Number: (7722-84-1); (79-21-0)

TEST LAB: Clean Earth Technologies, LLC

SUBMITTER: Clean Earth Technologies, LLC

GUIDELINE: 830 Guidelines

COMMODITIES: Formulation

REVIEWER: Juan F. Negrón ORGANIZATION: AD

APPROVER: Karen P. Hicks APPROVED DATE: 6/6/07

COMMENT:

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TO: Marshall Swindell / Karen Leavy
PM Team 33
FROM: Juan F. Negrón, Chemist
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Antimicrobial Division (7510P)
THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobial Division (7510C)
THRU: Michele E. Wingfield, Chief
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CJ for KPH

APPLICANT: Clean Earth Technologies, LLC
Action code: A50
Due date: 02/08/08

Product Formulation
Active Ingredient(s)

	% by wt.
Hydrogen Peroxide	24.0
Peroxyacetic Acid	1.2

BACKGROUND:

On behalf of the registrant, Clean Earth Technologies, LLC, Technology Sciences Group is submitting a new pesticide application and included the 830 guideline. The non-integrated end-use product, "Peridox™ with the Electrostatic Decontamination System (EDS) as an Antimicrobial for Sterilization and Decontamination of Bacillus anthracis Spores on Non-porous and Porous Surfaces," is a portable surface decontamination technology that destroys biological warfare agents (BWAs), spores (anthrax), viruses, and toxins.

FINDINGS:

1. The Product Chemistry Reviewer has received the following documents:
 - Letters, dated 10/19/04, & 07/27/06.
 - A label, dated 08/01/06 (pin punch).
 - A study titled, "Product Properties – Group A." MRID # 464561-01.
 - A study titled, "Product properties – Group B." MRID # 464561-02.
 - A study titled, "PERIDOX TM Response to EPA Product Chemistry Review EPA File Symbol 81073-R; DP Barcode D313279; May 20, 2005." MRID # 466320-01.
 - A study titled, "PERIDOX TM Product properties – Group B." 830.7300 Density MRID # 466320-02.
 - A study titled, "PERIDOX TM Product properties – Group B." 830.7100 Viscosity guideline. MRID # 466320-04.
 - A study titled, "PERIDOX TM Product properties – Group B." Storage & Corrosion studies. MRID # 465455-01.
 - Emails, dated 05/08/07 & 05/29/07, from Erin Tesch.
 - Data matrix, dated 07/27/06.
 - Confidential Statements of Formula (CSFs), dated 08/15/05, 01/26/05, & 05/31/07, for the basic formulation.
2. The CSFs, dated 08/15/05, & 01/26/05, for the basic formulation are obsolete.
3. The CSF, dated 05/31/07, for the basic formulation is revised.
4. The CSF and the label have the same nominal.
5. See confidential appendix CBI.

CONCLUSION:

The CSF, dated 05/31/07, for the basic formulation is acceptable. The registrant submits the 830 Group "A & B" guidelines and are acceptable. The Agency waives the storage stability and corrosion characteristics studies. The Agency suggested updating the certified limits for the AIs (see finding #5).

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [X]
- Are all TGAIs used registered? Yes [] No []
- Integrated formulation system []
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [x] No []

c. Physical state of product: Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [x] No []

e. The NCs and CLs are acceptable. Yes [X] No []

f. Active ingredient(s)	<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
Hydrogen Peroxide	24.0	23.3	24.7
Peroxyacetic Acid	1.2	1.1	1.3

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [] No [] Not applicable [X]
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes [] No [] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ No ☐

b. The formula contains one of the following:

- | | | |
|--|------------------------------|--|
| • 10% or more of a petroleum distillate: | Yes ☐ | No ☒ |
| • 1.0% or more of methyl alcohol: | Yes ☐ | No ☒ |
| • sodium nitrite at any level: | Yes ☐ | No ☒ |
| • a toxic List 1 inert at any level: | Yes ☐ | No ☒ |
| • arsenic in any form: | Yes ☐ | No ☒ |

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes ☐ No ☐ Not applicable ☒

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes ☐ No ☐ Not applicable ☒

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes ☒ No ☐

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes ☐ No ☐

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	464561-01
830.1600 Description of Materials	A	464561-01
830.1620 Production Process ²	NA	
830.1650 Formulation Process ³	A	464561-01
830.1670 Formation of Impurities ⁴	NA	464561-01
830.1700 Preliminary Analysis ⁵	NA	464561-01
830.1750 Certified Limits ⁶	A	464561-01
830.1800 Analytical Method ⁷	A	464561-01
830.1900 Submittal of Samples	[Samples are to be provided upon request.]	

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information

²For MP/EP products produced by an integrated formulation system.

³For products from a TGA1 or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	Colorless	464561-02
830.6303 Physical State	A	Liquid	464561-02
830.6304 Odor	NA		
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	Strong oxidant.	464561-02
830.6315 Flammability/Flame Extension	A	Not flammable	464561-02
830.6316 Explodability	A	Not explosive.	464561-02
830.6317 Storage Stability	A	From EPA Reg #81073-1. Similar product.	465455-01
830.6319 Miscibility ¹	A	To be mixed with water only.	464561-02
830.6320 Corrosion Characteristics	A	From EPA Reg #81073-1. Similar product.	465455-01
830.6321 Dielectric Breakdown Voltage	A	Not intended to be used around electrical equipment.	464561-02
830.7000 pH ²	A	1.3	464561-02
830.7050 UV/Visible Absorption	NA		
830.7100 Viscosity	A	1.27 centipoise @ 25 C	464561-02 466320-04
830.7200 Melting Point/Melting Range	NA		
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	A	1.113g/ml or 9.24 lb/gal.	464561-02 466320-02
830.7370 Dissociation Constants in Water	NA		
830.7550/830.7560/830.7570 Partition Coefficient	NA		
830.7840/830.7860 Water Solubility	NA		
830.7950 Vapor Pressure	NA		

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

¹If product is an emulsifiable liquid

²If product is dispersible with water

Page 8 is not included in this copy.

Pages through are not included in this copy.

The material not included contains the following type of information:

 Identity of product inert ingredients.

 Identity of product impurities.

 Description of the product manufacturing process.

 Description of quality control procedures.

 Identity of the source of product ingredients.

 Sales or other commercial/financial information.

 A draft product label.

 The product confidential statement of formula.

 Information about a pending registration action.

 FIFRA registration data.

 The document is a duplicate of page(s) .

 The document is not responsive to the request.

 Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.

 Attorney-Client Privilege.

 X Claimed Confidential by submitter upon submission to the Agency.

 Internal Deliberative Information.

* The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
