



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

FEB - 4 2011

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Earth Laboratories, Inc.  
1101 Eat Diamond Avenue  
Evansville, IN 47711

Attention: David Swain  
Agency for Earth Laboratories, Inc.

Subject: Peroxy HDOX minor formulation and labeling amendment  
EPA Reg. No. 84198-1  
Amendment Application Dated November 9, 2010

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. The Agency has not objection to the proposed alternate formulation.

The Agency notes that while the proposed Confidential Statement of Formulation (CSF) for alternate formulation dated 11/09/10 is acceptable, the alternate formulation does not have a unique identification. Therefore, this alternate formulation will supersede the previous alternate formulation. For further details please see the attached chemistry review.

The proposed request to add additional language to the label for use as a Disinfectant/ Fungicide/ Virucide in Fogging or Misting Decontamination system is unacceptable. This proposed use is a new use pattern which must be reviewed by the Agency. Should the Company like to apply for this new use they must submit a protocol proposing a test method to prove the efficacy of the product. The Agency is currently evaluating fogging and misting as use patterns and encourages the Company to meet with the Agency prior to submitting an application.

The Agency approves the following changes made to the label:

- On page five:
  - The addition of the word "carpets" under the heading "For Use as a Cleaner" is approved by the Agency.
- On page six:
  - The addition of the words "Carpet Cleaning" and "Carpet Spot and Pre-spray" are approved by the Agency.

- On page 7:
  - Addition of the phrase “Non-refillable container. Do not reuse or refill this container.

A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

A copy of the chemistry review is attached. If you have any questions concerning this letter, please contact Abigail Downs at (703) 305-5259.

Sincerely,



Marshall Swindell  
Product Manager (33)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Note to Agency: Text appearing in parenthesis ( ) or brackets [ ] is optional text. {Bracketed text} is for administrative purposes only and will not appear on final printed label.

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# PEROXY HDOX

[MULTI-SURFACE] [ONE-STEP] [DISINFECTANT]  
[SANITIZER] - [CLEANER] - [DEODORIZER]  
[\*VIRUCIDAL] - [FUNGICIDAL]

[Peroxy HDOX is a multi-purpose, germicidal, <sup>+</sup>virucidal, and fungicidal cleaner and deodorizer that disinfects or sanitizes (non-food contact surfaces), cleans, and removes malodors for hard, non-porous, inanimate surfaces]

<b>ACTIVE INGREDIENT:</b>	
Hydrogen Peroxide.....	6.70%
<b>OTHER INGREDIENTS:</b> .....	<b>93.30%</b>
<b>TOTAL:</b> .....	<b>100.00%</b>

## KEEP OUT OF REACH OF CHILDREN WARNING

See additional precautionary statements on [back] [side] [left] [right] [panel] of label [below].

EPA Reg. No. 84198-1  
EPA Est. No. 84198-IN-001

Net Contents:

Manufactured by:  
Earth Laboratories, Inc.  
1101 E. Diamond Avenue  
Evansville, IN 47711  
(866) 203.0535  
www.earthlaboratories.com

REGISTERED  
EPA REGISTRATION NO. 84198-1  
EPA EST. NO. 84198-IN-001  
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Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
amended, for the reasons set  
forth in the registration,  
registered under EPA Reg. No.  
84198-1

[PRODUCT OF THE USA]

Expiration Date: {may appear on label or on container}

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**Recommended Use (Locations):**

Peroxy HDOX is a multipurpose germicidal, <sup>†</sup>virucidal, and fungicidal cleaner and deodorizer that disinfects or sanitizes, cleans, and removes malodors in one labor saving step. Recommended for use in:

- |                       |                  |                            |
|-----------------------|------------------|----------------------------|
| Hospitals             | Schools          | Airports                   |
| Nursing Homes         | Universities     | Tanning Salons             |
| Health Care Settings  | Gymnasiums       | Retail Facilities          |
| Hotels & Motels       | Locker Rooms     | Warehouses                 |
| Cruise Ships          | Restrooms        | Commercial Facilities      |
| Dormitory Rooms       | Fitness Centers  | Industrial Facilities      |
| Temporary Housing     | Day Care Centers | Public Forums & Facilities |
| Households            | Office Buildings | Auditoriums                |
| Public Transportation | Casinos          | Churches                   |

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**Recommended Use (Surfaces):**

Peroxy HDOX cleans, disinfects, is fungicidal, is <sup>†</sup>virucidal, or sanitizes the following hard nonporous, inanimate, non-food contact surfaces when used as directed:

- |   |   |
|---|---|
| Floors, Walls, Ceilings                     | Plastic & Metal Pipes                         |
| Windows, Glass, Mirrors                     | Quarry Tile, Natural Stone, Sealed Grout      |
| Doors, Door Handles                         | Vinyl & Plastic                               |
| Toilets <sup>1</sup> & Urinals <sup>1</sup> | Stainless Steel, Aluminum, Brass, Soft Metals |
| Sinks, Counter tops, Fixtures               | Production & Materials Handling Equipment     |
| Tables, Chairs, Bed Frames                  | Office Equipment                              |
| Painted Surfaces                            | Fitness Equipment                             |
| Glazed Porcelain & Ceramic                  | [Metal Condensing Coils]                      |
| Baked Enamel                                |   |

This product when used as directed as a cleaner can be used on all surfaces not harmed by water.

<sup>1</sup> Non-water covered areas.

**For Use as a Cleaner/Disinfectant/Fungicide/Virucide:**

**Disinfectant:** Peroxy HDOX, when [used as directed at] [diluted] [10 ounces of concentrate] [product] [per gallon of water] [used concentrated] is effective against *Pseudomonas aeruginosa* [ATCC 15442], *Staphylococcus aureus* [ATCC 6538], *Salmonella enterica* [ATCC 10708], *Streptococcus pneumoniae* [ATCC 6303], *Escherichia coli* [ATCC 11229], Methicillin Resistant *Staphylococcus aureus* MRSA [ATCC 33592], & Community Associated Methicillin Resistant *Staphylococcus aureus* CA-MRSA (USA400) [NRS 123] in the presence of 200 ppm hard water, 5% soil load and a 10 minute contact time on hard non-porous inanimate surfaces.

**Fungicidal:** Peroxy HDOX, when [used as directed at] [diluted] [10 ounces of concentrate] [product] [per gallon of water] [used concentrated] is effective against *Trichophyton mentagrophytes* [ATCC 9533] in the presence of 200 ppm hard water, 5% soil load, and a 10 minute contact time on hard non-porous inanimate surfaces.

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**†Virucidal:** Peroxy HDOX, when [used as directed at] [diluted] [10 ounces of concentrate] [product] [per gallon of water] [used concentrated] is effective against Influenza Type A (Hong Kong) [ATCC VR-544] and Respiratory syncytial virus (RSV) [ATCC VR-26] in the presence of 200 ppm hard water, 5% soil load and a 10 minute contact time on hard non-porous inanimate surfaces.

Kills HIV-1 [AIDS virus] [HTLV-III<sub>B</sub>, Advanced Biotechnologies, Columbia, MD] when [used as directed] [diluted] [at 5 ounces of Peroxy HDOX concentrate] [product] [per gallon of water] [used concentrated] in the presence of 200 ppm hard water on hard non-porous inanimate surfaces with a 5 minute contact time.

**Sanitizing:** Peroxy HDOX, when [used as directed at] [diluted] [5 ounces of concentrate] [product] [per gallon of water] [used concentrated] is effective as a non-food contact sanitizer against Staphylococcus aureus [ATCC 6538] and Enterobacter aerogenes [ATCC 13048] in the presence of 200 ppm hard water, 5% soil load and a 5 minute contact time on hard non-porous inanimate surfaces.

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**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

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**WARNING:** Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear goggles or face shield when handling product concentrate such as when making use dilutions. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Causes moderate eye irritation. Avoid contact with eyes or clothing.

*{The following will be used only on labels with dilution instructions}*

[Note: After Peroxy HDOX is diluted in accordance with the directions for use, safety glasses and goggles are not required. [Peroxy HDOX] [Product], after dilution in accordance with the directions for use, is non-irritating.]

**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, then continue rinsing. Call a poison control center or doctor for treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

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**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 doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

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**DIRECTIONS FOR USE**

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

with the Federal Law Code, Paragraph and Sub-paragraph...  
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**This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that [1] is introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, or [2] contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.**

**For Use as a Cleaner/Disinfectant/Fungicide/Virucide:**

Dilute 10 ounces of concentrate per gallon of water. Thoroughly wet hard non-porous inanimate surface with the use-solution. The use-solution can be applied with a coarse spray, cloth, mop, ~~brushing~~, or by soaking. For sprayer applications use a coarse spray device 6-8 inches from the surface. Let use-solution remain on surface for a minimum of 10 minutes, wipe clean and allow to air dry. If unusually heavy soil deposits exist, pre-clean with Peroxy HDOX (as directed for use as a cleaner) prior to disinfecting. Replace mop bucket solution daily.

Peroxy HDOX kills HIV-1 when used as directed at 5 oz. of concentrate per gallon of water in the presence of 200 ppm hard water on hard, non-porous, inanimate surfaces with a 5 minute contact time.

~~For Use as a Disinfectant/Fungicide/Virucide/Decontaminating/Decontamination System:~~

~~Do not enter the room to be [decontaminated] [disinfected] during the [decontamination] [disinfecting] process.~~

~~The [Product System Name] must be used according to the instruction described in the User Guide supplied with the [Product System Name]. [Dilute 10 ounces of concentrate]~~

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~~per gallon water) [Use Concentrated]. The [Product Name] releases [concentrated] disinfectant solution from the [Product System Name] into the room. The disinfectant solution must remain on surfaces for a minimum of 10 minutes, wipe clean and allow to air dry. If unusually heavy soil deposits exist, pre-clean with Peroxy HDOX (as directed for use as a cleaner) prior to disinfecting.~~

**\*KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 [HIV-1] [associated with AIDS].

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 [AIDS Virus] OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

**Personal Protection:** Disposable latex or vinyl gloves, gowns, face masks, and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

**Cleaning Procedures:** Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of Peroxy HDOX.

**Contact Time:** Allow surface to remain wet for 5 minutes to kill HIV-1. Use a 10 minute contact time for all other organisms claimed.

**Disposal of Infectious Material:** Blood / body fluids should be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

**For Use as a Cleaner/Sanitizer:**

Dilute 5 ounces of Peroxy HDOX concentrate per gallon of water. Thoroughly wet hard, non-porous, inanimate surface with the use-solution. The use-solution can be applied with a coarse spray, cloth, mop, or by soaking. For sprayer applications use a coarse spray device 6-8 inches from the surface. Let use-solution remain on surface for a minimum of 5 minutes, wipe clean and allow to air dry. If unusually heavy soil deposits exist, pre-clean with Peroxy HDOX (as directed for use as a cleaner) prior to sanitizing. Replace mop bucket solution daily.

**For Use as a Cleaner:**

Peroxy HDOX can be used on all surfaces not harmed by water. The use-solution can be applied with a coarse spray, cloth, mop, soaking, or with use of the proper equipment. This product works exceptionally well as a cleaner/spotter on grouted floors walls and carpets. Recommended Dilutions are listed below:

**GREEN DILUTION (Light Duty)**

1/2 oz of Concentrate per gallon Water

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PEROXY HDOX  
REGISTERED TRADEMARK  
OF THE  
FMC CORPORATION

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**Spray & Wipe (Windows, Mirrors, Stainless Steel, Countertops)**

- Floor Mopping
- Auto Scrubbing
- Carpet Cleaning

**YELLOW DILUTION**

(Medium Duty)

5 oz of Concentrate per gallon Water

- Spray & Wipe
- Bathroom Cleaning
- Tile & Grout Cleaning
- Odor Control (Urine, Garbage, & Room Space Spray)
- Mold & Mildew Stains
- Carpet Spot & Pre-spray

**RED DILUTION**

(Heavy Duty)

10 oz of Concentrate per gallon Water

- Spray & Wipe
- Bathroom Cleaning
- Tile & Grout Cleaning
- Odor Control (Urine, Garbage, & Room Space Spray)
- Mold & Mildew Stains
- Carpet Spot & Pre-spray

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**For Use as a Deodorizer:**

Peroxy HDOX can be used as a deodorizer. For general deodorizing, dilute 5 oz. of Peroxy HDOX concentrate per gallon of water. For high level deodorizing dilute 10 oz. of Peroxy HDOX concentrate per gallon of water. Apply to hard non-porous surface to eliminate unpleasant odors.

{For sizes 1 gallon or less}

**STORAGE AND DISPOSAL**

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

Store in original container in areas inaccessible to small children. Store between 35° and 85° in dry, well ventilated area away from chemicals, direct light, heat, or open flame. Do not mix with other cleaning or disinfecting products. Keep securely closed. Offer for recycling, if available. Non-refillable container. Do not reuse or refill this container. Dispose of container according to Federal, State, and Local laws and regulations.

{For sizes over 1 gallon}

**STORAGE AND DISPOSAL:**

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

**PESTICIDE STORAGE:**



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Store in original container in areas inaccessible to small children. Store between 35° and 85° in dry, well ventilated area away from chemicals, direct light, heat, or open flame. Do not mix with other cleaning or disinfecting products. Keep securely closed.

**PESTICIDE DISPOSAL:**

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. For more information on the disposal of unused, unwanted product and the clean up of spills, contact the EPA Regional Office or the Manufacturer for guidance.

**CONTAINER DISPOSAL:**

Non-refillable container. Do not reuse or refill this container. Offer for recycling [or reconditioning], if available. Dispose of container according to Federal, State, and Local laws and regulations.

**ENVIRONMENTAL HAZARDS**

*{for containers of 5 gallons or 50 lbs. or more}*

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 the permitting agency 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 of the EPA.

[Additional Information about this product can be found at [www.earthlaboratories.com](http://www.earthlaboratories.com) or via telephone at (866) 203.0535]

~~(See User's Guide on subsequent pages for Fogging/Misting/Disinfection System.)~~

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