

# U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Antimicrobials Division (7510C) 1200 Pennsylvania Avenue NW Washington, D.C. 20460

NOTICE	OF P	ESTIC	IDE:

x Registration

Reregistration

(under FIFRA, as amended)

El	PA	Re	g
N	um	ber	:

Date of Issuance:

84198-1

MAY 2 2 2008

Term of Issuance:

Name of Pesticide Product: Peroxy

HDOX

Name and Address of Registrant (include ZIP Code):

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

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
- 2. Make the labeling changes listed below before you release the product for shipment:
  - a. Add the phrase "EPA Registration Number 84198-1."

Signature of Approying Official:

Date:

Marshall Swindell

**Product Manager-33** 

Regulatory Management Branch I

Antimicrobials Division (7510P)

MAY 2 2 2008

- 4. Submit the Storage and Stability and Corrosion Characteristic studies at the end of the one year study.
- 5. The proposed label states the product can be used to deodorize hard, non-porous surfaces. To satisfy DIS/TSS-16 requirements, the label must be revised to provide adequate dosage recommendations and complete directions for use of the product as a deodorizer.
  - 6. ATCC designation numbers are required in one of the following locations:

On the data matrix
On the master label (as optional text)
As the final page of the master label (as optional text)

- 7. On pages 4, 5, and 8 of the product label, revise the phrase, "course spray", to read, "coarse spray".
- 8. On page 7 of the product label under the "Container Disposal" section, include container disposal options. The product label includes only a recycling option.
  - 9. Revise the Precautionary Statements to read as follows:

Warning: Cause substantial but temporary eye injury. Do not get in eyes or on clothing. Wear goggled 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. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum using tobacco or using the toilet.

10. Add the following statement to the "First Aid" statements to read as follows:

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 further treatment advice.

11. The Agency does not stamp labeling designed for bottles intended to contain the diluted pesticide product. We however do provide guidance for the content of such labeling. Our comments will be forwarded to you under a separate correspondence.

The Confidential Statement of Formula dated January 4<sup>th</sup>, 2008, is acceptable.

12. Delete the phrase, "Kitchen equipment", as a use site. This site is considered a food contact surface use. Additionally, on pages 2, 4, & 5 the phrase" All food contact surfaces such as appliances and kitchen countertops must be rinsed with potable water." This product is not cleared for use on food contact surfaces at all, regardless of the use of potable water rinse.

- 13. On page 4, delete the word "OR" that appears between the sentences, "This product is not for use on medical......equipment surfaces" and "This product is not to be used as a terminal .....high level disinfections."
- 14. On pages 5 and 6, delete the phrases, "Carpet & Upholstery (Spotting, Extraction Clean, & Rinse)" and "Carpet Spotting & Pre-Spray". These are not acceptable use patterns for a disinfectant/sanitizer designed for use on hard, nonporous surfaces. Your proposed use on carpets & upholstery represents use on porous surfaces. EPA considers that users will infer that this disinfectant/sanitizer product will also disinfect/sanitize these porous surfaces. This type of claim is only permitted if acceptable efficacy has been received by the Agency.
- 15. Submit three (3) copies of the final printed label prior to releasing this product for sale.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Marshall Swindell Product Manager 33

Regulatory Branch I

Antimicrobials Division (7510P)

Enclosure: (Stamped Labeling)

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

01032008

PEROXY HDOX

# [MULTI-SURFACE] [ONE-STEP] [DISINFECTANT] [SANITIZER] - [CLEANER] - [DEODORIZER] [†VIRUCIDAL] - [FUNGICIDAL]

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

ACTIVE INGREDIENT:	
Hydrogen Peroxide	6.70%
OTHER INGREDIENTS:	93.30%
TOTAL:	

# KEEP OUT OF REACH OF CHILDREN WARNING

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

EPA Reg. No. 84198-R 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

[PRODUCT OF THE USA]

with COMMENTS in EPA Leafler Downed: MAY 2 2 2008

Under the Federal is a stricted, Propieted, and Rodermans Act as amended, for the personal registered under EPA lieg. No.

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

in parenthesis () or brackets [] is optional text. Note to Agency: Text app. keted text is for administrative purposes only and will not appear on final printed label. 01032008

# Recommended Use (Locations):

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

Schools Hospitals 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** Churches Casinos

### 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 Windows, Glass, Mirrors Doors, Door Handles Toilets1 & Urinals1 Sinks, Counter tops, Fixtures Tables, Chairs, Bed Frames Painted Surfaces Glazed Porcelain & Ceramic **Baked Enamel** 

Plastic & Metal Pipes

Quarry Tile, Natural Stone, Sealed Grout

Vinvl & Plastic

Stainless Steel, Aluminum, Brass, Soft Metals

Production & Materials Handling Equipment

Office Equipment Fitness Equipment

[Metal Condensing Coils]

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

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 is effective against Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella enterica, Streptococcus pneumoniae, Escherichia coli, Staphylococcus aureus MRSA, & Staphylococcus aureus CA-MRSA (USA400) in the presence of 200 ppm hard water, 5% soil load and a 10 minute contact time on hard nonporous inanimate surfaces.

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

Under the Federal inexacteds, Pungicide, and Rodontada Act as amended, for the perfecte.

<sup>†</sup>Virucidal: Peroxy HDOX, when [used as directed at] [diluted] 10 ounces of concentrate [product] per gallon of water is effective against Influenza Type A (Hong Kong) and Respiratory syncytial virus (RSV) 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] when [used as directed] [diluted] at 5 ounces of Peroxy HDOX concentrate [product] per gallon of water 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] [diluted] at 5 ounces of concentrate [product] per gallon of water is effective as a non-food contact sanitizer against Staphylococcus aureus and Enterobacter aerogenes in the presence of 200 ppm hard water, 5% soil load and a 5 minute contact time on hard non-porous inanimate surfaces.

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Harmful if swallowed. Avoid contact of concentrate with eyes. Wear protective eyewear such as safety glasses or goggles. 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.

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. 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.

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

ACCEPTED
with COMMENTS
in EPA Lates Dosed:

MAY 2 2 2008

Under the Federal Installed.

Puncicide, and Rodents de Act as amended, as the passage, No. 198-188.

Note to Agency: Text appe in parenthesis () or brackets [] is optional text. { \_\_\_\_keted text} is for administrative purposes only and will not appear on final printed label. 01032008

#### **DIRECTIONS FOR USE**

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

with COMMENTS in EPA Locar Dated.

This product is not for use on medical device or medical equipment surfaces

Under the Federal lass acticate,
Fungicide, and Rodenstrate Act as
amended, for the pessions,
registered under EPA Reg. No.

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 course spray, cloth, mop, or by soaking. For sprayer applications use a course 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.

\*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, or eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Note to Agency: Text app in parenthesis () or brackets [] is optional text. | keted text} is for administrative purposes only and will not appear on final printed label. 01032008

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 course spray, cloth, mop, or by soaking. For sprayer applications use a course 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 course spray, cloth, mop, soaking, or with use of the proper equipment. This product works exceptionally well as a cleaner/spotter on an account grouted floors and walls. Recommended Dilutions are listed below:

#### GREEN DILUTION ..

(Light Duty)

'½ oz of Concentrate per gallon Water Spray & Wipe (Windows, Mirrors, Stainless Steel, Countertops) Floor Mopping Auto Scrubbing

#### **RED 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

RED DILUTION (Heavy Duty) 10 oz of Concentrate per gallon Water with COMPARTS in EPA Later Dosed:

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Spray & Wipe Bathroom Cleaning Tile & Grout Cleaning

Odor Control (Urine, Garbage, & Room Space Spray) Mold & Mildew Stains

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Pungicide, and Rodenticade Act as amended, for the president, registered under EVA freg. No.

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{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° Fahrenheit and 85° Fahrenheit 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.

{For sizes over 1 gallon}
STORAGE AND DISPOSAL:

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

#### PESTICIDE STORAGE:

Store in original container in areas inaccessible to small children. Store between 35° Fahrenheit and 85° Fahrenheit 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:

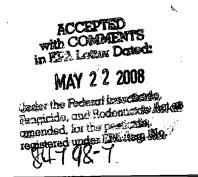
Offer for recycling [or reconditioning], if available.

#### **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 or via telephone at (866) 203.0535]



Note to Agency: Text appear on final printed label. 01032008

cketed text) is for administrative

{Use Dilution Spray Bottle Label Light}

#### Peroxy HDOX

Diluted and filled by customer

**GREEN DILUTION** 

LIGHT DUTY

**CLEANER** 

# KEEP OUT OF REACH OF CHILDREN

Mantener Alejado Del Alcance De Los Ninos

#### Directions for Use:

The use solution can be applied with a course spray, cloth, mop, soaking, or with use of the proper equipment. This product works exceptionally well as a cleaner/spotter on clothing, carpeting, upholstery, grouted floors and walls.

Diluted with ½ oz of Concentrate per gallon Water

Spray & Wipe (Windows, Mirrors, Stainless Steel, Countertops)
Floor Mopping
Auto Scrubbing
Carpet & Upholstery (Spotting, Extraction Clean, & Rinse)

#### **Precautionary Statements**

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

Precaución: Despues de que el producto se diluya de acuerdo con las direcciones para el uso, las gafas de seguridad y los anteojos no se requieren. Peroxy HDOX, despues de la dilusion de acuerdo con las direcciones para el uso, es no-irritante.

Manufactured by:
Earth Laboratories, Inc.
866.203.0535
www.earthlaboratories.com

Note to Agency: Text app. g in parenthesis () or brackets [] is optional text. cketed text is for administrative purposes only and will not appear on final printed label. 01032008

{Use Dilution Spray Bottle Label Medium / Heavy Duty}

# Peroxy HDOX

The product in this container is diluted as directed on the Peroxy HDOX label, EPA Reg. No. 84198-R

**RED DILUTION** 

Medium Duty (5 oz per gallon water) CLEANER

Heavy Duty (10 oz per gallon) CLEANER/DISINFECTANT/SANITIZER

Active Ingredient:

Hydrogen Peroxide...... 6.70% (before dilution)

#### KEEP OUT OF REACH OF CHILDREN

Mantener Alejado Del Alcance De Los Ninos

Directions for Use

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

Disinfectant/Sanitizer:

Follow the directions for use on the Peroxy HDOX container label when applying this product.

Cleaner:

Follow the cleaner directions for use on the Peroxy HDOX container label when applying this product.

For Use as a Cleaner:

Spray & Wipe Cleaning

Bathroom Cleaning

Tile & Grout Cleaning

Carpet Spot

Carpet Pre-Spray

Odor Control

Mold & Mildew Stains

Uso Para:

Limpieza Del Aerosol Y Del Trapo Limpieza Del Cuarto de baño

Limpieza Del Azulejo Y De la Lechada

Control del Odor

Manchas del molde y del moho

Manufactured by:

Earth Laboratories, Inc.

866.203.0535

www.earthlaboratories.com

## **Precautionary Statements**

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HMIS RATING	Salud Del Grado de HMIS	
HEALTH – 0	Salud – 0	
REACTIVITY – 0	Reactividad – 0	
FLAMMABILITY – 0	Inflamabilidad - 0	