



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 16, 2017

Jennifer M. Richardt President Earth Laboratories, Inc. 1101 East Diamond Ave. Evansville, IN 47711

Subject: PRIA Label Amendment – Adding Efficacy Claims for Norovirus and Feline Calicivirus Product Name: PEROXY HDOX EPA Registration Number: 84198-1 Application Date: December 7, 2016 Decision Number: 524663

Dear Ms. Richardt:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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

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with FIFRA section 6. If you have any questions, please contact Zebora Johnson by phone at (703) 308-7080, or via email at johnson.zebora@epa.gov.

Sincerely,

Alu Milus

John Hebert, Chief Regulatory Management Branch 1 Antimicrobial's Divison (7510P) Office of Pesticide Programs

Enclosure: Accepted Label



and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 84198-1

# PEROXY HDOX

# [MULTI-SURFACE] [ONE-STEP] [DISINFECTANT] [SANITIZER] - [CLEANER] - [DEODORIZER] [<sup>†</sup>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]

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



# **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

[PRODUCT OF THE USA]

Expiration Date: [may appear on label or container]

#### **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, but not exclusive to:

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

### **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. The following areas and surfaces represent, but are not all-inclusive of, typical habitats for the bacteria, virus, and/or fungi kill claims for this product:

Floors, Walls, Ceilings Windows, Glass, Mirrors Doors, Door Handles Toilets<sup>1</sup> & Urinals<sup>1</sup> Sinks, Counter tops, Fixtures Tables, Chairs, Bed Frames Painted Surfaces Glazed Porcelain & Ceramic Baked Enamel Plastic & Metal Pipes Quarry Tile, Natural Stone, Sealed Grout Vinyl & 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.

<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 is effective against Pseudomonas aeruginosa [ATCC 15442], Staphylococcus aureus [ATCC 6538], Salmonella enteric [ATCC 10708], Streptococcus pneumonia [ATCC 6303], Escherichia coli [ATCC 11229], Staphylococcus aureus – MRSA [ATCC 33592], & Community Associated Methicillin Staphylococcus aureus CA-MRSA (USA 400) [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.

Peroxy HDOX, when [used as directed at] [diluted at] [10 oz. of concentrate][product][per gallon of water][used concentrated] is effective against Feline Calicivirus, and Norovirus in the presence of 200 ppm hard water, 5% soil load and a 5 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.

<sup>†</sup>**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]) 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-IIIB [when used as directed at] [5 ounces of 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.

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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.

**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.

### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product is not for use on medical device surfaces.

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, Norvirus, [and] [&] Feline Calicivirus 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.

**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, Norovirus, [and][&] Feline Calicivirus. 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 grouted floors walls and carpets. Recommended Dilutions are listed below:

GREEN DILUTION

(Light Duty) <sup>1</sup>/<sub>2</sub> oz of Concentrate per gallon Water 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 Spotting & 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 Spotting & Pre-Spray

## 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

{Note to Agency: Text appearing in parenthesis or brackets is done to show optional text}. 12042016 updated 05112017

{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: 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 or via telephone at (866) 203.0535]