

69268-2

03-10-2010

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Brennis Consulting
Agent for Envirox LLC
6628 Birchleigh Way
Alexandria, VA 22315

MAR 03 2010

Attention: Robert Brennis
Regulatory Manager

Subject: Notification
H2Orange2 117 Concentrate
EPA Reg. No. 69268-2
Amendment Letter dated January 24, 2010

This will acknowledge receipt of your notification for the aforementioned product labels, submitted under the provisions of FIFRA Section 3(c) (9). Based on a review of the submitted material, the following apply:

- Updating container disposal language per PR Notice 2007-4

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

A handwritten signature in black ink, which appears to read "M. Swindell", is written over the typed name.

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)



EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other (Notification)

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 69268- 2	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Envirox H2Orange2 117 Concentrate	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Envirox LLC 1938 E. Fairchild Street Danville, IL 61832 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input checked="" 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

- ☐ Amendment - Explain below. ☐ Final printed labels in response to Agency letter dated _____
- ☐ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application
- ☒ Notification - Explain below. ☐ Other - Explain below

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

This is a simple notification for an additional brand name. We are adding the brand name "Sanitizing Surface Cleaner"

The storage and disposal language needed to be updated according to PR Notice 2007-4.

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 or 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 the 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:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other
*Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container

3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container ounces of product 22 Ounces Net weight	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name: Robert S. Brennis, Brennis Consulting Services LLC, 6628 Birchleigh Way, Alexandria, VA 22315	Title Agent for Envirox LLC	Telephone No. (Include Area Code) 703-922-6677
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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.

2. Signature 	3. Title Agent for Envirox LLC	6. Date Application Received (Stamped)
4. Typed Name Robert S. Brennis	5. Date January 24, 2010	

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Brennis Consulting Services LLC

6628 Birchleigh Way, Alexandria, VA 22315
703-922-6677
Brennis.bob@gmail.com

January 24, 2010

U.S. Environmental Protection Agency
Document Processing Desk (7504P)
Room S-4900
1200 Pennsylvania Ave. NW
Washington, D.C. 20460-0001

ATTENTION: Marshall Swindell
Product Manager, Team 33

SUBJECT: Envirox LLC
H2Orange2 117 Concentrate (EPA Reg. No. 69268-2)
Notification – Updated Storage and Disposal Language

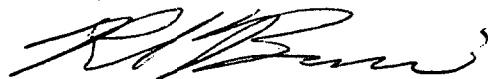
Dear Mr. Marshall Swindell:

On behalf of Envirox LLC, I am submitting a label notification for their product, **H2Orange2 117 Concentrate (EPA Reg. No. 69268-2)**. This is a simple notification for updating the label with appropriate storage and disposal language as identified in PR Notice 2007-4. These changes (as highlighted) provides for appropriate storage and disposal language for reusable plastic containers.

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 or 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 the 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.

If you have any questions about the enclosed submission, please contact me by telephone at 703-922-6677 or by e-mail at Brennis.bob@gmail.com.

Sincerely,



Robert S. Brennis
Agent for,
Envirox LLC.

Highlighted 4/5

H₂ORANGE₂ CONCENTRATE 117

(OPTIONAL LOGO/MARKETING STATEMENT)

OXIDIZING MULTI PURPOSE CLEANER, DEGREASER & SANITIZER
(NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR
HARD, NON-POROUS SURFACES, CARPET EXTRACTION FOR CLEANING,
DEODORIZING, AND KILLING ODOR CAUSING BACTERIA

ACTIVE INGREDIENT	
Hydrogen peroxide	3.95%
OTHER INGREDIENTS	96.05%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN**CAUTION****SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

EPA Reg. No. 69268-2

EPA Est. No. 69268-II.-001

Envirox, LLC
1938 E. Fairchild St., Danville, IL 61832

NET CONTENTS:

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream 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.

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus.
- This product (Product Name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.

PRECAUTIONARY STATEMENTS - HAZARDS TO **HUMAN** AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye damage. Harmful if swallowed, absorbed through the skin, or inhaled. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, 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 eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

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

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.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage

STORAGE AND DISPOSAL

IN CASE OF SPILL: To clean up spill, flood area with large quantities of water. Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer.

STORAGE: Store this product in a cool dry area, away from direct sunlight and heat to avoid deterioration. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials. Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose.

PESTICIDE DISPOSAL: Do not contaminate food or feed by storage, disposal or cleaning of equipment. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: **If Empty:** Do not reuse container. Place in trash or offer for recycling if available. **If Partially Filled:** Call your local solid waste for disposal instructions. Never place unused product down any indoor or outdoor drain. Triple rinse container (or equivalent) promptly after emptying. **Triple rinse as follows:** Empty remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Refillable containers - cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. If in plastic bag with original box, discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burning, stay out of smoke.

Questions? Call 1-800-281-9604

DIRECTIONS FOR USE

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

H2Orange2 Concentrate 117 Manual & Dispenser Dilution, when used as directed as a sanitizer, kills 99.99% of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, H2Orange2 Concentrate 117 Manual & Dispenser Dilution, kills the following viruses in 5 minutes at room temperature (20+/-1° C): Herpes simplex virus Type 2, Influenza A2/Japan, HBV (Hepatitis B Virus) and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents, except HIV-1, are killed as stated, use 10 oz. of H2Orange2 Concentrate 117 Manual & Dispenser Dilution (10 parts to 118 parts) of cold tap water.

CLEANING AND SANITIZING: Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace mop-bucket solution daily.

TO USE AS A SANITIZER AND VIRUCIDE IN BATHROOMS: Add 10oz. of H2Orange2 Concentrate 117 Manual & Dispenser Dilution (10 parts to 118 parts) of cold tap water for sinks, faucets, counters, urinals, toilets (non-water covered surfaces) and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace mop-bucket solution daily. Follow instructions for inanimate, hard, non-porous surfaces.

TO USE AS A SANITIZER AND VIRUCIDE ON INANIMATE, HARD, NON-POROUS SURFACES: Add 10 oz H2Orange2 Concentrate 117 Manual & Dispenser Dilution (10parts per 118 parts) of cold tap water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer with a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace mop-bucket solution daily.

HIV-1 and HBV: To kill HIV-1 in 5 minutes at room temperature (20-25°C) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1oz. of H2Orange2 Concentrate 117 Manual & Dispenser Dilution per gallon (1 part to 127 parts) of cold tap water. To kill HBV in 5 minutes at room temperature (20-25°C) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 10 oz. of H2Orange2 Concentrate 117 Manual & Dispenser Dilution (10 parts to 118 parts) of cold tap water. For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1 Associated with AIDS) or HBV (Hepatitis B Virus).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV (HEPATITIS B VIRUS) AND HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy Duty Cleaning Solution.

Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label. For HBV, use concentration of 10 oz per gallon (10 parts to 118 parts). Leave surfaces wet for 5 minutes.

Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

DEODORIZING

For general deodorizing, use 2 oz of H2Orange2 Concentrate 117 Manual & Dispenser Dilution per gallon (2 parts to 126 parts) of cold tap water. Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 oz of H2Orange2 Concentrate 117 Manual & Dispenser Dilution per gallon (10 parts to 118 parts) of cold tap water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold stains, and surfaces in musty closets.

CLEANING SOLUTION DILUTIONS & APPLICATIONS**LIGHT DUTY** (1 Oz / gal) GREEN (bottle or label)

Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)

General wipe down cleaner
Mopping solution for Bathroom and Kitchen floors
General carpet spot remover

HEAVY DUTY (10 Oz / gal) RED (bottle or label)

Bathroom, shower room, tile & grout cleaner
Urine and garbage odor eliminator
Pre-spray for carpet extraction
General degreaser
Heavy soil wipe down cleaner
Heavy carpet spot remover
Cleans Mold & mildew stains

SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)

Renovation of tile & grout surfaces
Difficult urine & garbage odor destruction
Scuff marks and stubborn stains
Cleans heavy mold & mildew stains

CARPET EXTRACTION**For Cleaning, Deodorizing and Killing Odor Causing Bacteria**

For the extraction of dirt, soil, and other contaminants in carpets, use 10 oz of H2Orange2 Concentrate 117 Manual & Dispenser Dilution per gallon (10 parts per 118 parts) of cold tap water. Pre-spray the carpet (+00sq ft per gallon of RTU Dilution), let sit for 10 minutes, then extract with cold tap water only.