

69268-2

05/05/2010

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



Office of Pesticide Programs

MAY - 5 2010

Brennis Consulting Services LLC
c/o Envirox LLC
6628 Birchleigh Way
Alexandria, VA 22315

Attention: Robert S. Brennis

Subject: Envirox LLC
EPA Registration No. 69268-2
Notification Dated April 14, 2010

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9).

Proposed Notification

- To Add the Labeling claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)

General Comment

Based on a review of the submitted material, the following comments apply:

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

Conditions:

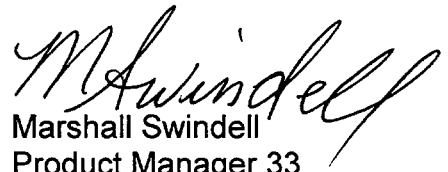
Please note that at the next printing of the label, you must reformat the label to place the instructions for the 2009 H1N1 Influenza A Virus within the Directions for Use section.

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EPA Registration No. 69268-2

The title "nonrefillable" must precede the instruction under the Container Disposal instructions. Refer to the PR Notice 2007-4 for further instructions.

If you have any questions or comments concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



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

Brennis Consulting Services LLC

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

April 16, 2010

U.S. Environmental Protection Agency
Document Processing Desk
One Potomac Yard
2777 South Crystal Drive (South Building)
Arlington, VA 22202

ATTENTION: Wanda Henson
Product Manager, Team 32

SUBJECT: Envirox LLC
H2Orange2 Concentrate 117 (EPA Reg. No. 69268-2)
Label Notification

Dear Ms.Henson:

On behalf of Envirox LLC, I am submitting a notification for, **H2Orange2 Concentrate 117 (EPA Reg. No. 69268-2)** within the parameters provided in the **Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)**.

This is a notification of H1N1 claims based on Influenza A virus claims already accepted for this product and per PR Notice 95-2. This notification is consistent with the provisions of PR Notice 95-2 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 18U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 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. A label is enclosed identifying the specific changes.


I have enclosed a label with a acceptable claims highlighted and a finished label (without the highlighting).

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

 EPA United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other (Notification)	OPP Identifier Number
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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

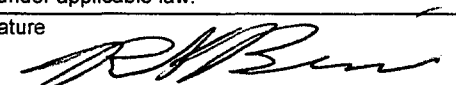
<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 On behalf of Envirox LLC, I am submitting a notification for, **H2Orange2 Concentrate 117 (EPA Reg. No. 69268-2)** within the parameters provided in the **Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)**. This is a notification of H1N1 claims based on Influenza A virus claims already accepted for this product and per PR Notice 95-2. This notification is consistent with the provisions of PR Notice 95-2 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 18U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 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. A label is enclosed identifying the specific changes.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
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			<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	

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
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.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Envirox LLC	
4. Typed Name Robert S. Brennis	5. Date April 16, 2010	

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.

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MASTER LABEL

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.

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 I (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 10 118 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 (400sq ft per gallon of RTU Dilution), let sit for 10 minutes, then extract with cold tap water only.