

JUN 30 2005

Envirox, LLC  
1938 E. Fairchild Street  
Danville, IL 61382

AGENT: ChemReg International, LLC  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192-2383

Attention: Janine Polizzi

Subject: H<sub>2</sub>Orange<sub>2</sub> Concentration 117  
EPA Registration No. 69268-2  
Your Notification Dated June 7, 2005

This will acknowledge receipt of your notification to remove "or more" from the following sentences under the Directions for Use: "...when used as directed as a sanitizer, kills 99.99% from the following..." and "when used as directed as a virucide, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 kills the following viruses in 5 minutes...", submitted under the provisions of FIFRA Section 3(c)(9). 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 added to your file.

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

Sincerely



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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

287

Please read instructions on reverse before completing form

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 69268-2	2. EPA Product Manager Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) H2Orange2 Concentrate 117	PM # 33	
5. Name and Address of Applicant (Include ZIP Code) Envirox, LLC 1938 E. Fairchild Street Danville, IL 61382  <input 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.)

Notification of correction to sanitizer and virucidal claims sections of master label, per PR Notice 98-10, Section II (N).

Removed "or more" from the following statements under Directions for Use: from the sentence "when used as directed as a sanitizer, kills 99.99% of the following..." and from the sentence "When used as directed as a virucide, H2Orange2 Concentrate 117 kills the following viruses in 5 minutes...".

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 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:				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
<b>*Certification must be submitted</b>		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		5. Location of label directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____	

**Section IV**

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Janine M. Polizzi	Title ChemReg International, LLC	Telephone No. (Include Area Code) 703-492-2717

**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 ChemReg International, LLC Authorized representative for Envirox LLC
4. Typed Name Janine Polizzi	5. Date June 7, 2005

6. Date Application Received
(Stamp)

# ChemReg<sup>®</sup>

INTERNATIONAL, LLC

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1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

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WEB SITES: www.chemreg.com  
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**JANINE M. POLIZZI**

June 7, 2005

Document Processing Desk (NOTIF)  
U.S. Environmental Protection Agency (7504C)  
Office of Pesticide Programs  
Room 266A, Crystal Mall 2  
1801 South Bell Street  
Arlington, VA 22202-4501

Attn: Marshall Swindell (PM 33)

Re: H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117, EPA Reg. No. 69268-2  
Notification per PR 98-10 for Other Revisions

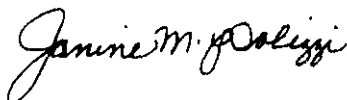
Dear Marshall:

On behalf of our client, EnvirOx, LLC, we are submitting the enclosed notification per PR 98-10 (Section II.N) for the above product. On the most recent EPA-stamped label (1/18/2005), we have noted two errors pertaining to the sanitizer and virucidal claims. These errors are in the first paragraph below Directions for Use, on page 3 of the master label.

Therefore, we are removing "or more" from the sentence "when used as directed as a sanitizer, kills 99.99% of the following..." and from the sentence "When used as directed as a virucide, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 kills the following viruses in 5 minutes...".

Enclosed please find EPA Form 8570-1, one (1) copy of the master label and one (1) copy of the master label with the revisions highlighted. Please contact me by phone or email if there are any questions or concerns about this notification.

Sincerely,



Janine Polizzi

cc: EnvirOx, LLC

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**CONSULTANTS TO SUCCESS<sup>®</sup>**

**Expertise in Toxicology, Residue and Product Chemistry, Environmental Fate, Efficacy, Registration Strategies and Implementation, Regulatory Compliance, Label Development, Exposure and Risk Assessments, Data Citation and Compensation, Study Design and Monitoring.**

## H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE CLEANER, DEGREASER & SANITIZER  
(NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR  
HARD, NON-POROUS SURFACES

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-IL-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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

**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:** Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE:** Do not contaminate water, food, and or feed by storage. 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.

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

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. 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 burned stay out of smoke or if in plastic bottles, triple rinse or equivalent and recycle.

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.

**H<sub>2</sub>Orange<sub>2</sub> Concentrate 117**, 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, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 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 are killed as stated, use 10 oz. of product concentrate per gallon 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 10 oz. of product concentrate per gallon 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 ounces of product concentrate per gallon 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 precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 per 127 parts of cold tap water). To kill HBV in 5 minutes at room temperature (20-25°C ) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 10 oz / gallon. 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 or Super 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/gallon and 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 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 per 126 parts of cold tap water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 118 (10 oz / gallon) 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

**OPTIONAL MARKETING STATEMENTS:** (one or more or none of the following may appear)

New! (for first 6 months only)

Registered for control of [Hepatitis B Virus]/[HBV]

Registered to kill [Hepatitis B Virus]/[HBV]

Starburst design as graphic which may contain the optional marketing statement(s): eg,



ESL: 1/13/2005

Notif: 4/18/2005, 4/25/2005, 6/07/2005