



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JAN 13 2005

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Elizabeth Anne Brown
Regulatory Agent for,
c/o Envirox LLC
1990 Old Bridge Road, Suite 201
Lake ridge, VA 22192-2383

Subject: H,Orange, Concentrate 117
EPA Registration Number 69268-2
Your Submission Dated November 19th, 2004
EPA Received Dated November 19th, 2004

The amendment application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, to add the Hepatitis B virus to the product labeling, is acceptable.

EFFICACY

The submitted data (MRID Nos. 463095-01 and 463095-2) support the use of the product, H,Orange, Concentrate 117, as a virucide against the Hepatitis B virus on hard, non-porous surfaces for a contact time of 5 minutes in the presence of organic soil at a 1:12.8 dilution at room temperature.

LABELING

The proposed label claims that the product, H2orange2 Concentrate 117, is an effective virucide against HBV(Hepatitis B virus) in 5 minutes at room temperature at a concentration of 10 oz. product per gallon of cold temperature on inanimate, hard, non-porous surfaces. This claim is acceptable.

On page 2, under the "First Aid" instructions, change the phrase , "gentle stream on water" to read "gentle stream of water."

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

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell".

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

2/s

H₂ORANGE₂ 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.

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:

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amended, for the pesticide,
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69268-2

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 eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

If on skin: Wash with plenty of soap and water. Get medical attention.

If swallowed: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

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

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69268-02

DIRECTIONS FOR USE

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

H₂Orange₂ Concentrate 117, when used as directed as a sanitizer, kills 99.99% or more 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 kills the following viruses in 5 minutes or more 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 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 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 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 H₂Orange₂ 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 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 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.

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DEODORIZING

For general deodorizing, use 2 parts H₂Orange₂ 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 H₂Orange₂ 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

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DRAFT Amendment – not EPA approved: 6-28-2004