

1677-228

8/21/2009

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 1677-228

Date of Issuance: AUG 21 2009

Term of Issuance:

Conditional

Name of Pesticide Product:

OXY-PAK

NOTICE OF PESTICIDE:

[x] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Eliot Harrison
Lewis & Harrison
c/o for Ecolab Inc.
122 C Street NW
Suite # 740
Washington DC, 20001

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(a) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
a. Revise the "EPA Registration Number to read, EPA Reg. No. 1677-228".

Signature of Approving Official:

Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

[Handwritten signature of Marshall Swindell]

Date:

AUG 21 2009

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- b. Your Storage and Disposal language must be revised. Your application (EPA Form 8570-1) list multiple container sizes (96 oz, 1, 4, 30, 50 gal, and bulk). Based on PR Notice 2007-4, the language must incorporate residue removal instructions that are comparable the container type. Therefore, the following instructions must be added:

For those containers less than 5 gallons

Under the **Pesticide Disposal** section, insert the statement “Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment 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”

Or, for those sections greater than 5 gallons

Triple rinse as follows: Empty the remaining contents into application equipment or mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip the container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two or more times.

Refillable Containers (Bulk)

In the **Pesticide Disposal** section, insert the statement, “Refill the container with pesticide only. Do not reuse this container for any other purpose.

In the **Pesticide Disposal** section, insert the statement “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.

In the **Pesticide Disposal** section, instructions for cleaning each refillable container prior to disposal are required. The residue removal instructions must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment. Please refer to PR Notice 2007-4, Appendix C (All Other Products in Refillable Container) for more information pertaining to what you could include in your labeling as appropriate residue removal statement.

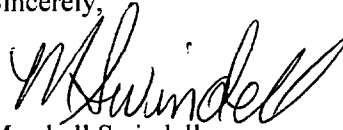
- c. Change “Interox Hydrogen Peroxide” to “Interox 35% Hydrogen Peroxide”.
- d. Change “Inert Ingredients” to “Inert Ingredient”.
- e. Change “Surfaces should be exposed to “OXY-PAK for a period . . . “ to “Surfaces must be exposed to “OXY-PAK for a minimum period . . . “.
- f. Delete the phrase “contact times and temperatures may vary depending on the specific type of aseptic food packaging line.”
- g. Delete “Vaporization” from the list of application methods, no data was submitted to support this method, nor a risk assessment conducted to support vaporization.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,



Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: (Stamped Label)

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OXY-PAK

COMMERCIAL STERILANT FOR ASEPTIC PACKAGING OF FOODS

COMMERCIAL STERILANT FOR ASEPTIC MANUFACTURING AND
PACKAGING EQUIPMENT FOR FOOD PROCESSING

Active Ingredient:

Hydrogen Peroxide	35%
Inert Ingredients.....	65%
Total.....	100.0%

ADVERTISED
UNDER FEDERAL PESTICIDE CONTROL ACTS
REGISTERED UNDER EPA REG. NO.
AUG 21 2009
 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 1677-228

**KEEP OUT OF REACH OF CHILDREN
DANGER**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Wash thoroughly after handling with soap and water, and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse. Wear a mask or pesticide respirator jointly approved by Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.

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 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor for treatment advice. Have a 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 by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

**FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026
OUTSIDE NORTH AMERICA, CALL 1-651-222-5352**

Have a product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

PHYSICAL AND CHEMICAL HAZARDS: Strong oxidizing agent. Corrosive. Contact with combustibles may cause fire. Contamination may cause rapid decomposition and generation of large quantities of oxygen and heat.

ENVIRONMENTAL HAZARDS: This product is toxic to birds, fish and aquatic invertebrates. 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 permitting authority 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.

DIRECTIONS FOR USE:

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

COMMERCIAL STERILIZATION

OXY-PAK can be used to achieve commercial sterility of food-packaging materials and food processing equipment.

COMMERCIAL STERILIZATION OF FOOD PACKAGING MATERIALS

Commercially sterilize food packaging materials with undiluted *OXY-PAK*. Apply *OXY-PAK* by immersion, coarse spray, mist, ~~vaporization~~ or circulation techniques, as appropriate, to food packaging materials. Surfaces ~~should~~ ^{must} be exposed to *OXY-PAK* for a period of 20 seconds at 75°C; ~~contact times and temperatures may vary depending on the specific type of aseptic food packaging line.~~ This product when used per label directions is effective against *Bacillus subtilis* and *Clostridium sporogenes*.

OXY-PAK may be used to sterilize containers for aseptic food packaging of low acid foods that has a schedule process accepted by FDA. The aseptic food processing operation must comply with all applicable FDA regulations, including, but not limited to 21 CFR parts 108, 110, and 113 and/or 114. Use in an aseptic food processing operation includes testing required for the process validation.

COMMERCIAL STERILIZATION OF MANUFACTURING, FILLING AND PACKAGING EQUIPMENT FOR FOOD PROCESSING

Prior to use of this product, remove gross soil particles from equipment surfaces, thoroughly clean surfaces and then follow with a potable water rinse. Commercially sterilize pre-cleaned manufacturing, filling and packaging equipment with undiluted *OXY-PAK* by immersion, coarse spray or circulation techniques, as appropriate. Surfaces ~~should~~ ^{must} be exposed to *OXY-PAK* at a temperature of 75°C for 20 seconds, unless a longer time is specified by the governing food processing authority. This product when used per label directions is effective against *Bacillus subtilis* and *Clostridium sporogenes*.

ACCEPTED
with COMMENTS
in EPA Letter Dated

AUG 21 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

1677-228

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This product may be used for Aseptic Packaging of Low Acid Foods that has a scheduled process by FDA. The aseptic food processing operations must comply with the all applicable FDA regulations, including, but not limited to 21 CFR parts 108, 110, 113 and /or 114. Use in an aseptic food processing operation includes testing required for the process validation.

This product is not for use as a sterilant on medical devices.

STORAGE & DISPOSAL:

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE AND DISPOSAL.

STORAGE: Product should be kept cool and in a vented container to avoid any explosion hazard.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

(≤ 55 gallons rigid) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying (Totes) Verify the tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

**FOR COMMERCIAL USE ONLY
STRONG OXIDIZING AGENT**

- Net Contents: 96 ounces
- 1 U.S. Gal. (3.78 L)
- 4 U.S. Gal (15.1 L)
- 30 U.S. Gal (113.5 L)
- 50 U.S. Gal (189 L)

**ACCEPTED
WITH COMMENTS
in EPA Letter Dated**

AUG 21 2009
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1677-228

Manufactured by:
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

EPA Reg. No. 1677 –

EPA Est.:1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2 (R), 1677-TC-1 (D),
1677-OH-1 (H), 1677-IL-2 (J), 1677-PR-1 (B), 1677-CA-1 (S), 1677-NJ-1 (W),
1677-GA-1 (M), 1677-WV-1 (V)

Superscript refers to first letter of date code