

68660-10

8/20/2009

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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:  
 68660-10

Date of Issuance:  
 AUG 20 2009

Term of Issuance:  
**Conditional**

Name of Pesticide Product:  
 Interox 35% Hydrogen Peroxide

**NOTICE OF PESTICIDE:**  
 Registration  
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Eliot Harrison  
 Lewis & Harrison  
 c/o for Solvay Chemicals 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. 68660-10".

Signature of Approving Official:

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

Date:

AUG 20 2009

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- b. Your Storage and Disposal language must be revised. Your application (EPA Form 8570-1) list multiple container sizes (1gal to 55 gal, tote, and tank truck). 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 (Totes and Tank Trucks)**

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.

**Non-Refillable Containers**

- Under the **Pesticide Disposal** section, insert the statement “Triple rinse container (or equivalent) promptly after emptying”.
- Triple rinse container (or equivalent) promptly after emptying.

**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  $\frac{1}{4}$  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.
- Under the **Container Disposal** section, insert the following language: Offer containers for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.
- Under the **Container Disposal** section, insert the statement "Nonrefillable container. Do not reuse or refill this container".

**Refillable Containers**

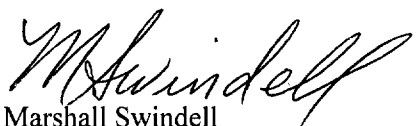
- In the **Pesticide Disposal** section, insert the statement, "Refill the container with pesticide only. Do not reuse this container for any other purpose.
  - In the **Pesticide Disposal** section, insert the statement "Cleaning the container before final disposal is the responsibility of the person 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. Revise your Directions For Use statement "Apply Interox Hydrogen Peroxide . . . food processing line." to read "This is a ready-to-use solution. To sterilize precleaned surfaces apply Interox 35% Hydrogen Peroxide on the interior and/or exterior of food containers and closure systems (caps, seals, etc.,) or appropriate food processing equipment surfaces. Use immersion, coarse spray or circulation techniques as appropriate to sterilize the equipment. Apply this product (i.e., 350,000 ppm of hydrogen peroxide) at a minimum temperature of 75 degrees C. The hydrogen peroxide solution must remain in contact with the surface for a minimum of 20 seconds; longer contact times may be required in certain aseptic food processing lines.
- d. Change "Interox Hydrogen Peroxide" to "Interox 35% Hydrogen Peroxide".
- e. Change "Inert Ingredients" to "Inert Ingredient".

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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.

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)

**ASEPTIC PACKAGING  
COMMERCIAL STERILIZATION OF FOOD-CONTACT SURFACES AND FOOD PROCESSING EQUIPMENT**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER: CORROSIVE.** Causes irreversible eye damage. Causes skin burns. Do not get in eyes, on skin, or clothing. May be fatal if swallowed or inhaled. Do not breathe vapor or spray mist. Wear a respirator with an organic vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P, or HE prefilter. Consult the MSDS for information about respirators and cartridges that have been tested and shown to be effective in removing hydrogen peroxide from air. Wear chemical goggles, rubber gloves, and protective clothing when handling this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash before reuse.

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

Manufactured and Distributed by:  
**SOLVAY CHEMICALS, INC.**  
3333 Richmond Avenue, Houston TX 77098  
USA (713) 525 - 6500  
For emergency, call: CHEMTREC®  
(800) 424 - 9300

EPA Reg. No.: 68660 - XX  
EPA Est. No.: 070411-TX-001

**Interox® 35% Hydrogen Peroxide**

<b>ACTIVE INGREDIENT:</b>	
Hydrogen Peroxide .....	35.0%
<b>INERT INGREDIENTS</b> .....	65.0%
<b>Total</b> .....	<b>100.0%</b>

**KEEP OUT OF REACH OF CHILDREN  
STRONG OXIDIZING AGENT  
DANGER / PELIGRO**

FIRST AID
<p><b>IF IN EYES:</b> - Hold eyelids open and rinse slowly and gently for 15 - 20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.</p> <p>- Call a poison control center or doctor for treatment advice.</p>
<p><b>IF ON SKIN:</b> - Take off contaminated clothing.</p> <p>- Rinse skin immediately with plenty of water for 15 - 20 minutes.</p> <p>- Call a poison control center or doctor for treatment advice.</p>
<p><b>IF INHALED:</b> - Move person to fresh air.</p> <p>- If not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth - to - mouth, if possible.</p> <p>- Call a poison control center or doctor for treatment advice.</p>
<p><b>IF SWALLOWED:</b> - Call poison control center or doctor immediately for treatment advice.</p> <p>- Drink promptly large quantities of water if able to swallow.</p> <p>- Do not induce vomiting unless told to do so by a poison control center or doctor.</p> <p>- Do not give anything by mouth to an unconscious person.</p>
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>
<p><b>NOTE TO PHYSICIAN:</b> Probable mucosal damage may contraindicate the use of gastric lavage.</p>

Net Wt.: type here pounds. Weight per gallon: 9.44 lb.

Lot. No. type here

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into oceans, lakes, streams, ponds, estuaries or public waters unless the components of this product are specifically identified in a NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage plant authority. For guidance contact your State Water Board or Regional Office of the U.S. Environmental Protection Agency. This product is toxic to birds, fish and aquatic invertebrates.

**STORAGE AND DISPOSAL**

**DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL**

**STORAGE**

Store in original vented container in a dry location away from heat and out of direct sunlight. In case of fire involving product, use water. In case of large quantities of spilled material, dike with sand or earth. Dilute with large quantities of water.

**PESTICIDE DISPOSAL**

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture, or rinsate, is a violation of Federal Law. For additional information, refer to the product Material Safety Data Sheet.

**CONTAINER DISPOSAL** Plastic Containers (300 gallon tote) and Stainless Steel Containers (300 gallon tote, 4500 gallon tank trucks, 20,000 gallon railcars): Return for reuse.

Plastic Containers (15, 30, and 55 gallon drums): Triple rinse (or equivalent) then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

*Handwritten:* AUG 20 2009  
EPA Reg. No. 68660-XX  
EPA Est. No. 070411-TX-001  
Federal Insecticide, Fungicide, and Rodenticide Act  
EPA Reg. No. 68660-10

*Handwritten:* 5046

# Interox® 35 % Hydrogen Peroxide

## DIRECTIONS FOR USE

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

## ASEPTIC PACKAGING

### COMMERCIAL STERILIZATION OF FOOD-CONTACT SURFACES AND FOOD PROCESSING EQUIPMENT

Interox® Hydrogen Peroxide is an effective commercial sterilant to treat food-contact surfaces and food processing equipment when used in accordance with equipment manufacturers' directions.

This product may be used to achieve commercial sterility of food packaging materials and food processing equipment.

Apply Interox® Hydrogen Peroxide on the interior and/or exterior of food containers and closure systems (caps, seals, etc) or appropriate food processing equipment surfaces. Apply 350,000 ppm of hydrogen peroxide at a temperature of 75° C. The hydrogen peroxide solution must remain in contact with the surface for 20 seconds; contact times and temperatures may vary depending on the specific type of aseptic food processing line.

Validated food processing systems that have control over the contaminant load on food packaging surfaces or food processing equipment prior to fill may vary concentration, temperature, and/or contact time to achieve commercial sterility. Such use must comply with applicable FDA regulations, including but not limited to, 21 CFR parts 108, 110, 113 and 114.

The use of this product in aseptic food processing operations includes testing required for process validation. Food subject to these FDA regulations may not be sold in a treated package until the scheduled process for the food processing operation has been accepted by the FDA.

Interox® Hydrogen Peroxide meets or exceeds the hydrogen peroxide monograph of the Food Chemicals Codex (FCC).

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

For technical assistance on using this product for this application, contact the aseptic packaging equipment manufacturer, supplier or SOLVAY CHEMICALS, INC. at 713-525-6500.

EPA Reg. No.: 68660 - XX  
EPA Est. No.: 070411-TX-001

Manufactured and Distributed by: SOLVAY CHEMICALS, INC.  
3333 Richmond Avenue, Houston, TX 77098 USA  
(713) 525 - 6500 For emergency, call CHEMTREC® (800) 424 - 9300

ACCEPTED  
with COMMENTS  
by EPA Letter # 68660-XX

AUG 20 2009

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, it is unlawful to sell or  
distribute any pesticide which does not

68660-10

WPC