

68660-11

12/24/2008

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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: 68660-11

Date of Issuance: DEC 24 2008

Term of Issuance:

Conditional

Name of Pesticide Product:

Proxitane AHC

NOTICE OF PESTICIDE:

[x] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Wendy McCombie
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. 68660-11".

Signature of Approving Official:

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

Handwritten signature of Marshall Swindell with initials MS and date 12/24/08

Date:

DEC 24 2008

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- b. Under the **Precautionary Statement** section, the following language must be incorporated, per the findings in the acute toxicity review (Goad, E. Acute Toxicity Review for EPA File Symbol 68660-RR, Oct 28, 2008):
- Do not breathe vapor or spray mist and wear a respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NOISH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NOISH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE pre-filter.
  - When handling, wear goggles or face shield, rubber gloves, chemically resistant coveralls or apron worn over long-sleeved shirt, long pants, socks and chemically resistant footwear. This language supersedes existing language in the statement.
  - Change "Remove contaminated clothing and wash before reuse" to read "Remove and wash contaminated clothing before reuse"
  - Change "before eating, drinking, chewing gum or using tobacco" to read "before eating, drinking, chewing gum, using tobacco or using the toilet."
  - Change "**eclosed** area" to read "**enclosed** area".
- c. Under the **First Aid** section, the following must be incorporated:
- In the "Note to Physician" statement, change "**Probably** mucosal damage" to read "**Probable** mucosal damage".
  - Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
  - Call the poison control center at 1-800-222-1222.
- d. An **Environmental Hazards** section was not included on the label and must be added (per 40 CFR 156.10(h)(2) [iii]). The Environmental Hazard statement provides the precautionary language advising of the potential hazards to the environment from transport, use, storage, or spill of the product. The section should be located under the general heading "Precautionary Statements" and it must have the heading "Environmental Hazards". Currently, part of the language for Environmental Hazards is located in your Storage and Disposal section. That language must be moved and properly stated.

The following statements must be incorporated under the **Environmental Hazards** section:

- 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 the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

- e. Under the "Manufactured [by][for]" section of the product label, change "333 Richmond Avenue" to read "3333 Richmond Avenue".
- f. The language for **Foot and Mouth Disease (Aphthovirus)** must be removed. Submitted data were deficient to support this claim (see Laniyan, I, Efficacy Review for Proxitane AHC, Nov 13, 2008).
- g. Under the sections, "**Environmental Surface Disinfection and Disinfection Use Rates for Viruses and Fungi**", change "product soak in on the treated surface" to read "product remain on the treated surface".
- h. Under the "**Storage and Disposal**" statement, the following changes must be incorporated, per the guidance from PR Notice 2007-4 and PR Notice 83-3:
  - In the **Pesticide Disposal** section, insert the statement "Triple rinse container (or equivalent) promptly after emptying".
  - Triple rinse container (or equivalent) promptly after emptying.
  - In 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.
  - Insert the statement "**Container Disposal**", 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.
  - In the **Container Disposal** section, per the guidance from PR Notice 2007-4, insert the statement "Nonrefillable container. Do not reuse or refill this container".

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)

ACCEPTED  
with COMMENTS  
to EPA Letter Dated

# PROXITANE® AHC

Liquid Disinfectant

One-Step Cleaner Disinfectant

For Industrial/Institutional/Animal Facilities/Farm Use Only

DEC 24 2008  
Under the Federal Insect  
Fungicide, and Rodenticide  
Act, amended, for the purpose  
of registration.

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Active Ingredients:

Hydrogen Peroxide.....22.75%  
Peroxyacetic Acid.....5.24%

Inert Ingredients: .....72.01%  
TOTAL: 100.00%

STRONG OXIDING AGENT

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

### PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. CORROSIVE. Causes irreversible eye damage. Causes skin burns. May be fatal if ingested or inhaled. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety glasses) chemical resistant apron or coveralls and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash before reuse. Do not enter an enclosed area without proper respiratory protection.

*Wear protective eyewear*

*Remove*

### PHYSICAL AND CHEMICAL HAZARDS

Strong oxidizing agent. Corrosive. Do not use in concentrated form. Mix only with water according to label instructions. Contact of concentrate with other disinfectants, cleaners, or other material may cause fire.

### FIRST AID

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

*Add Environmental Hazard Statement*

<b>If in eyes</b>	<ul style="list-style-type: none"> <li>Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15 – 20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If inhaled</b>	<ul style="list-style-type: none"> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Drink promptly large quantities of water.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
<b>CALL A POISON CONTROL CENTER OR PHYSICIAN IMMEDIATELY FOR EMERGENCY MEDICAL INFORMATION.</b>	
<b>NOTE TO PHYSICIAN:</b> Probably mucosal damage may contraindicate the use of gastric lavage.	

*Remove*

### 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. ~~Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, or public waters unless~~

*Remove*

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~~the components of this product are specifically identified in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage plant authority. 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, 4,500 gallon tank trucks, 20,000 gallon railcars):

Return for reuse.

Plastic containers (1 pint, 1 quart, and 1, 5, 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 by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Glass Containers (1 pint, 1 quart, and 1 gallon): Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

#### DIRECTIONS FOR USE

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

Proxitane<sup>®</sup> AHC is a broad spectrum disinfectant that is effective against both gram positive and gram negative bacteria, viruses, and fungi including *Staphylococcus aureus*, *Salmonella enterica*, *Trichophyton mentagrophytes*, Vesicular Stomatitis Virus, Porcine Respiratory and Reproductive Syndrome Virus, Influenza A Virus, Infectious Bovine Rhinotracheitis, Rhinovirus Type 37, Infectious Bursal Disease Virus, Newcastle Disease Virus, Avian Influenza Virus (H3N2) ~~and the foot-and-mouth disease virus (Aphthovirus)~~. Proxitane<sup>®</sup> AHC may be used in commercial, institutional, industrial, and veterinary environments to clean, disinfect, and deodorize hard, nonporous inanimate surfaces, such as the following:

- Floors, walls, and other nonporous surfaces, including tables, chairs, countertops, garbage cans, garbage bins, bathroom fixtures, sinks, bed frames, shelves, racks, carts, refrigerators, coolers, glazed tile, linoleum, vinyl, glazed porcelain, plastic (e.g., polypropylene and polyethylene) stainless steel, and glass.

- Schools, colleges, industrial facilities, dietary areas, office buildings, recreational facilities, and retail and wholesale establishments, pharmaceutical and cosmetic manufacturing facilities.
- Animal hospitals, veterinary clinics, animal life science laboratories, kennels, kennel runs, cages, feeding and watering equipment, pet shops, zoos, pet animal quarters, poultry premises, trucks, hatcheries, and livestock quarters.

#### Environmental Surface Disinfection

- Prepare the disinfectant use solution, by adding 2.04 oz of Proxitane<sup>®</sup> AHC to 5 gallons of water (provides 796 ppm hydrogen peroxide and 184 ppm peroxyacetic acid).
- For heavily soiled surfaces, remove gross filth and soils with a detergent or suitable cleaning product and then rinse surface with water.
- Apply the disinfectant use solution by wiping, mopping, or spraying (use a coarse spray device) onto the surface to be treated. Let the product soak in on the treated surface for at least 10 minutes and then allow to air dry.

#### Disinfection Use Rates for Viruses and Fungi

- Prepare the disinfectant use solution, by adding 1.92 oz of Proxitane<sup>®</sup> AHC to 5 gallons of water (provides 682 ppm hydrogen peroxide and 157 ppm peroxyacetic acid).
- For heavily soiled surfaces, remove gross filth and soils with a detergent or suitable cleaning product and then rinse surface with water.
- Apply disinfecting solution via wiping, mopping, or spraying (use a coarse spray device) onto the surface to be treated. Let the product soak in on the treated surface for at least 10 minutes and then allow to air dry.

#### Disinfection and Deodorizing of Animal Housing Facilities and Buildings, Farm Equipment, Poultry Premises, Coops, Trucks, and Crates

- Remove all animals/poultry from the facilities/items/areas to be disinfected.
- Remove gross soils, litter, droppings, etc. with a warm water flush or by sweeping.

3. Empty all troughs, racks, and other feeding and watering equipment.
4. Thoroughly clean all surfaces with detergent or cleaning solution and rinse with water.
5. Prepare a disinfecting solution by adding 2.04 oz of Proxitane® AHC to 5 gallons of water (provides 796 ppm hydrogen peroxide and 184 ppm peroxyacetic acid).
6. Make sure area is well-ventilated prior to initiating treatment.
7. To disinfect, saturate surfaces with disinfecting solution for at least 10 minutes.
8. Thoroughly scrub treated feed equipment (e.g., feed racks, troughs, fountains, etc.) with a detergent and rinse with water prior to reuse.
9. Keep animals/poultry out of treatment area and/or do not use treated equipment until solution has been completely absorbed and air dried.

**Poultry Hatchery Disinfection**

1. Remove any eggs, chicks, poultry and feeds along with all gross soils and other hatching-related debris.
2. Thoroughly clean all surfaces with an appropriate detergent or cleaning solution; then rinse with water.
3. Prepare a disinfecting solution by adding 2.04 oz of Proxitane® AHC to 5 gallons of water (provides 796 ppm hydrogen peroxide and 184 ppm peroxyacetic acid).
4. Make sure area is well-ventilated prior to initiating treatment.
5. Apply disinfecting solution via wiping, mopping, or spraying (use a coarse spray device onto the surface to be treated. Let the product soak in on the treated surface for at least 10 minutes and then allow to air dry.
6. Reintroduce eggs and chicks after all surfaces have dried.

**Fogging**

Proxitane® AHC is for disinfecting hard, nonporous surfaces in rooms as an adjunct to manual cleaning and disinfecting of room surfaces.

1. Before fogging, remove or protect all food products and packaging materials. Remove all animals/poultry from the facilities/items/areas to be fogged

2. Be sure the room is properly ventilated. All personnel must vacate the room during fogging and for at least two hours following the fogging treatment. Before personnel return to the treated area, make sure there is no strong odor of acetic acid present.
3. Fog areas using one quart per 1000 cubic feet of room area with a solution of 2.04 oz of Proxitane® AHC for every 5 gallons of water.
4. Let all surfaces drain thoroughly before resuming operations in the treated area.

**Manufactured [by] [for]:**  
 Solvay Chemicals, Inc.  
 333 Richmond Avenue  
 Houston TX 77098

Net Contents: \_\_\_\_\_

EPA Reg. No. 68660-\_\_

EPA Est. No. \_\_\_\_\_

ACCEPTED  
 WITH COMMENTS  
 in EPA Letter Dated  
 DEC 24 2008

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

68660-11

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