

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 16, 2020

Wendy A. McCombie Agent Solvay Chemicals Inc. 3737 Buffalo Speedway, Suite 800 Houston, TX 77098

Subject: Label Amendment: Emerging Viral Pathogens Claim Product Name: Proxitane AHC EPA Registration Number: 68660-11 Application Date: March 17, 2020 Decision Number: 561212

Dear Ms. McCombie:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-

09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

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- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
- 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.

i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:

- A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
- B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
- C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (<u>www.cdc.gov/hai/outbreaks</u>)

ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page

(www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).

A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large non-enveloped and enveloped.

B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.

4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

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5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Rhinovirus Type 37 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at <u>disinfectantslist@epa.gov</u>.

Sincerely,

Steven Snyderman

Steven Snyderman, Acting Product Manager 33 Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure: stamped label

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. CORROSIVE.

Causes irreversible eye damage and causes skin burns. Do not get in eyes, on skin, or on 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.

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. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

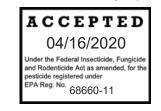
Remove and wash contaminated clothing before reuse.

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.

ENVIRONMENTAL HAZARDS

This product is toxic to birds, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the authority has been notified in writing. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage plant authority. For guidance contact your State Water Board or Regional Office of the U.S. Environmental Protection Agency.



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PROXITANE[®] AHC

Liquid Disinfectant One-Step Cleaner Disinfectant For Industrial/Institutional/Animal Facilities/Farm Use Only

Active Ingredients:

Hydrogen Peroxide	
Peroxyacetic Acid	5.24%
Inert Ingredients:	<u>72.01%</u>
TOTAL:	100.00%

STRONG OXIDING AGENT KEEP OUT OF REACH OF CHILDREN DANGER

FIRST AID

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

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 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.

If swallowed

- Call a poison control center or doctor immediately for treatment advice.
- Drink promptly large quantities of water.
- 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.

CALL THE POISON CONTROL CENTER at 800-222-1222 OR PHYSICIAN IMMEDIATELY FOR EMERGENCY MEDICAL INFORMATION.

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

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. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment of mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Drain application equipment for 10 seconds after the flow begins to drip. Repeat this procedure two moiré times.

CONTAINER DISPOSAL:

Plastic Containers (300 gallon tote) and Stainless Steel Containers (300 gallon tote, 4,500 gallon tank trucks, and 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). 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. <u>Glass Containers (1 pint, 1 quart, and 1 gallon)</u>: Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Solvay Chemicals, Inc. 3333 Richmond Avenue Houston TX 77098 USA (713) 525-6500 For Emergency, Call Chemtrec® (800) 424-9300

EPA Reg. No. 68660-11 EPA Est. No. 60156-IL-1

Net Wt: [enter weight here]

Lot No.: [enter lot here]

Weight per Gallon: 9.2 lbs.

DIRECTIONS FOR USE

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

Proxitane[®] 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 Virus, Rhinovirus Type 37, Infectious Bursal Disease Virus, Newcastle Disease Virus, and Avian Influenza Virus (H3N2). Proxitane[®] 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

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

Disinfection Use Rates for Viruses and Fungi

- 1. Prepare the disinfectant use solution, by adding 1.92 oz of Proxitane® AHC to 5 gallons of water (provides 682 ppm hydrogen peroxide and 157 ppm peroxyacetic acid).
- 2. For heavily soiled surfaces, remove gross filth and soils with a detergent or suitable cleaning product and then rinse surface with water.
- 3. Apply disinfecting solution via wiping, mopping, or spraying (use a coarse spray device) onto the surface to be treated. Let the product remain 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

- 1. Remove all animals/poultry from the facilities/items/areas to be disinfected.
- 2. 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 for:

EPA Reg. No. 68660-11 EPA Est. No. 60156-IL-1

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Emerging Viral Pathogen Claims

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

-Enveloped Viruses

-Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an	follow the directions for use for the following organisms on the label:
Enveloped Virus	Rhinovirus Type 37
Large, non-enveloped virus	Rhinovirus Type 37

Proxitane® AHC has demonstrated effectiveness against viruses similar to [name of enveloped/large, non-enveloped emerging virus] on hard, non-porous surfaces. Therefore, Proxitane® AHC can be used against [name of enveloped/large, non-enveloped emerging virus] when used in accordance with the directions for use against Rhinovirus Type 37 on hard, non- porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of enveloped/large, non-enveloped emerging virus]. Proxitane® ACH kills similar viruses and therefore can be used against [name of enveloped/large, non-enveloped emerging virus] when used in accordance with the directions for use against Rhinovirus Type 37 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

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