

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 4, 2014

Jennifer J. Klika HACCO, Inc. 110 Hopkins Drive Randolph, WI 53956

Subject: PRIA Label Amendment – (1) Adding claim for Porcine Epidemic Diarrhea Virus; (2) Supplemental Label for Porcine Epidemic Diarrhea Virus Product Name: BioPhene Liquid Disinfectant EPA Registration Number: 61282-53 Application Date: June 3, 2014 Decision Number: 491890

Dear Ms. Klika:

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.

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.

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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, please contact me by phone at (703) 308-8735, or via email at chao.julie@epa.gov.

Sincerely,

Mui Anne Che

Julie Chao, Acting Product Manager 34 Regulatory Management Branch II Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure: Stamped Accepted Label, Efficacy Review

BioPhene™ Liquid Disinfectant Page 1 of 8 October 15th, 2014

BioPheneTM Liquid Disinfectant

Disinfectant • Cleaner

 * Proven Effective as a One-Step Cleaner-Disinfectant in the Presence of 5% Organic Serum for Poultry, Swine , Animal Care Facilities, Livestock and Veterinary Uses.
 * DILUTION: 1 to 256 (one-half ounce per gallon)

ACTIVE INGREDIENTS:

o-Phenylphenol	
o-Benzyl-p-chlorophenol	
p-tert-Amylphenol	
OTHER INGREDIENTS:	
TOTAL:	

EPA Reg. No. 61282-53

EPA Est. No. 61282-WI-01

KEEP OUT OF REACH OF CHILDREN DANGER

See [Inside] [Side] Panels for Additional Precautionary Statements

Net Contents:

1 gallon	(3.785 liters)
2.5 gallons	(9.46 liters)
5 gallons	(18.93 liters)
55 gallons	(208 liters)

	ACCEPTED	
I	12/4/2014	
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under		
	EPA Reg. No. 61282-53	

Manufactured By: HACCO, Inc. 110 Hopkins Drive Randolph, WI 53956 BioPhene[™] Liquid Disinfectant Page 2 of 8 October 15th, 2014

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive: Causes irreversible eye damage. Harmful if swallowed, or absorbed through skin or inhaled. Do not get in eyes, on skin or clothing. Avoid contact with skin. Avoid breathing spray mist. Wear long-sleeved shirt and long pants, socks and shoes, goggles or face shield and chemical resistant gloves. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE): Pesticide handlers must wear: Longsleeved shirt and long pants, chemical resistant gloves (such as any waterproof material, rubber, etc.), wear protective eyewear (goggles, face shield, or safety glasses), shoes plus socks. In addition, when engaged in pouring this product, a respirator with either an organic vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE prefilter.

USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions are available for washables, use detergent and hot water. Keep and wash separately from other laundry. Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

FIRST AID				
Have Label When Obtaining Treatment Advice				
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, or 1-800-498-5743 immediately 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, or 1-800-498-5743 immediately for treatment advice. 			
If Inhaled:	 Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center, or doctor, or 1-800-498-5743 immediately for treatment advice. 			
 If Swallowed: Call a poison control center, or doctor, or 1-800-498-5743 immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. 				
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment. For 24-hour emergency information on this product, call 1-800-498-5743 (US & Canada) or 1-651-523-0318 (all other areas).				
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.				

PHYSICAL AND CHEMICAL HAZARDS:

Combustible. Do not use or store near heat or open flame.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. 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 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.

BioPhene[™] Liquid Disinfectant Page 4 of 8 October 15th, 2014

BACTERIA & FUNGI: Using A.O.A.C. Use Dilution test, BioPhene Liquid Disinfectant is an effective disinfectant in 400ppm hard water and 5% serum against the following bacteria and fungi.

Alcaligenes faecalis	Aspergillus fumigatus	
Brevibacter ammoniagenes	Brucella abortus	
Candida albicans	Enterobacter aerogenes	
Enterococcus faecium	Escherichia coli	
(Streptococcus faecalis)		
Klebsiella pneumoniae	Pasteurella multocida	
Pseudomonas aeruginosa	Salmonella choleraesuis	
Salmonella enteriditis	Salmonella schottmuelleri	
Shigella dysenteriae	Staphylococcus aureus	
Streptococcus pyogenes	Trichophyton	
	mentagrophytes	
Not approved for use in California against the following		
bacteria:	-	
Mycoplasma gallisepticum	Mycoplasma iners	

VIRUSES: Using accepted virus propagation and hard surface test methods, BioPhene Liquid Disinfectant is effective at 1:256 in 400ppm hard water and 5% serum against the following (**Not approved in California for use against the following viruses**):

Avian influenza	Avian laryngotracheitis	
Canine parvovirus	Infectious bronchitis	
Infectious bursal disease	Newcastle's disease	
(Gumboro)		
Parainfluenza	Porcine parvovirus	
Pseudorabies	Swine PRRS virus	
Transmissible gastroenteritis	Vesicular stomatitis virus	
Porcine Epidemic Diarrhea Virus		

DIRECTIONS FOR USE

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

BioPhene Liquid Disinfectant is a one-step germicide, fungicide, soapless cleaner and deodorant, effective in the presence of organic soil.

- To clean and disinfect hard non-porous surfaces, use 1/2 ounce of BioPhene Liquid Disinfectant per gallon of water (4 ml / liter). Apply liquid with a mop, sponge, cloth or bowl mop to thoroughly wet surfaces. Prepare fresh solutions daily or when solution becomes visibly dirty.
- To clean badly soiled areas use 1¹/₂ ounce per gallon of water (12 ml / liter).
- To disinfect, allow treated surfaces to stand for at least 10 minutes before wiping.
- To control mold and mildew growth on previously cleaned, hard, non-porous surfaces, use 1/2 ounce per gallon. Allow to dry without wiping. Reapply as new growth appears.

GENERAL FARM DISINFECTANT USES:

- (1/2 ounce per gallon) (4 ml / liter)
- (a) Remove all animals, poultry and feed from premises, trucks and enclosures.
- (b) Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities occupied or traversed by animals or poultry.
- (c) Empty all troughs, racks, and other feeding and watering appliances.
- (d) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- (e) Saturate all surfaces with the recommended solution for a period of 10 minutes.
- (f) Immerse all halters, ropes and other types of equipment used in handling and restraining animals or poultry, as well as the cleaned forks, shovels, and scrapers used for removing litter and manure, in the recommended use solutions.
- (g) Ventilate buildings, vehicles, trailers and other closed spaces. Do not house livestock or poultry or employ equipment until treatment has been absorbed, set or dried.
- (h) Thoroughly scrub treated feeding and watering equipment with detergent and rinse with potable water before reuse.

POULTRY HATCHERIES: BioPhene Liquid Disinfectant is effective for cleaning and disinfecting hatchers, setters, buggies, trays, racks, equipment, utensils and other environmental surfaces in avian hatcheries. After initial cleaning and disinfecting with BioPhene Liquid Disinfectant diluted 1/2 ounce per gallon (4 ml/ liter), rinse and reapply a fresh disinfecting solution. Do not rinse again. One step clean and disinfecting is not recommended in hatcheries.

SANITIZING HATCHING EGGS: Use 1/2 ounce per gallon (4 ml / liter) of BioPhene Liquid Disinfectant and apply by immersion, foaming, low pressure spraying, flushing or wet misting. Water temperatures from 75° F to 110° F (24° C to 44° C) are recommended. Use on hatching eggs only. Do not apply on eggs that are to be consumed.

VEAL, CALVING, HOG, CATTLE AND HORSE OPERATIONS: Between depopulations of facilities, cleaning and disinfection of pens, hutches, aisles, ventilation equipment, utensils and other environmental surfaces may be required. Flush soils from these areas and clean and disinfect with 1/2 ounce per gallon (4 ml / liter) of BioPhene Liquid Disinfectant. Take care to avoid spray and other contact with animals, feed or feed equipment or in water or watering devices. If spray is used on or contacts feeders or waterers, scrub them and rinse well with potable water before they are reused.

FARM BOOT BATH: Use one (1) ounce per gallon (8 ml / liter) in farm boot baths. Change solution daily and anytime it becomes visibly soiled. Use a nylon brush to clean soils from boots.

FOR HEALTH-CARE FACILITIES: (Not approved in California for the following uses): At 1/2 ounce per gallon of water (4 ml / liter), BioPhene Liquid Disinfectant is an effective cleaner and germicide for floors, walls, bedframes, bathroom fixtures, bathtubs, toilets, sinks, countertops in operating rooms, emergency rooms, patient rooms, laboratories, clinics and veterinary facilities.

BioPhene[™] Liquid Disinfectant Page 6 of 8 October 15th, 2014

FOR SCHOOLS, MOTELS, INSTITUTIONAL AND INDUSTRIAL USES: (Not approved in California for the following uses): At 1/2 ounce per gallon of water (4 ml / liter), BioPhene Liquid Disinfectant is an effective cleaner and disinfectant in areas that contain hard, non-porous surfaces: restrooms, shower and bath areas, exercise facilities and garbage storage areas.

FOR SPRAY APPLICATIONS: Following application as a low pressure or high-pressure spray, do not enter or allow others to enter treated area until sprays have dried.

APPLICATION RESTRICTIONS: Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

STORAGE AND DISPOSAL

Do Not Contaminate Water, Food, or Feed by Storage or Disposal PESTICIDE STORAGE - Store in a dry place no lower in temperature than 50°F or higher than 120°F.

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 – Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¹/₄ full with water. Replace and tighten closures. Tip 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 rinstate into application equipment of a mix tank or store rinstate for later use or disposal. Repeat this procedure two more times. Offer for recycling, if available. If not available, puncture and dispose in a sanitary landfill.

DISCLAIMER: To the extent permitted by applicable law, seller makes no representation or warranty, either express or implied, for results due to misuse, improper handling or improper storage of this material. Nor does Seller assume any responsibility for injury to persons, crops, animals, soil or property arising out of misuse, improper handling or improper storage of this material.

OR

LIMITED WARRANTY

To the extent permitted by applicable law, Neogen Corporation makes no warranty concerning uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label. To the extent permitted by applicable law, Neogen Corporation shall not be liable for (1) any consequential, incidental or special damages related in any way to this product or its uses, or (2) any damages related in any way to resistance to pesticides.

OR

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

To the extent permitted by applicable law Manufacturer and Seller warrant that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law this warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Manufacturer, and Buyer and User assume the risk of any such use. To the extent permitted by applicable law, MANUFACTURER AND SELLER MAKE NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE. To the extent permitted by applicable law, in no event shall Manufacturer or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF MANUFACTURER AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF THE MANUFACTURER OR SELLER, THE REPLACEMENT OF THE PRODUCT.

Manufacturer and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitations of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of Manufacturer.

For non-emergency (e.g., current product information), Call: **1-800-621-8829** BioPheneTM Liquid Disinfectant Page 8 of 8 October 15th, 2014

BioSentry[®] is a Registered Trademark of BioSentry, Inc.; Used Under Exclusive License by Neogen Corporation.

BioPhene[™] is a Trademark of Neogen Corporation.

Code (RN.RU.) RN.RU.

Alternate Brand Names:

BioSentry[®] BioPhene Disinfectant BioSentry[®] BioPhene

Optional Marketing Statements / Graphics:

Manufactured in the U.S.A. <American Flag Graphic> <Barn Graphic>



Supplemental Labeling

CONTAINS ADDITIONAL INFORMATION WHICH MAY NOT APPEAR ON PACKAGE LABEL.

This labeling must be in possession of the user at the time of application. Read the label affixed to the container for BioSentry BioPhene Disinfectant before applying. Use of BioSentry BioPhene Disinfectant according to this labeling is subject to the use precautions and limitations imposed by the label affixed to the container for BioSentry BioPhene Disinfectant.

This label expires 12/01/2017 and must not be used or distributed after that date

BioSentry[®] BioPhene™ Disinfectant

EPA Reg. No. 61282-53

For Effective Control of Porcine Epidemic Diarrhea Virus

KEEP OUT OF REACH OF CHILDREN DANGER

VIRUSES: Using accepted virus propagation and hard surface test methods, BioSentry BioPhene Disinfectant is effective at 1:256 in 400ppm hard water and 5% serum against the following

Avian influenzaAvian laryngotracheitisCanine parvovirusInfectious bronchitisInfectious bursal diseaseNewcastle's disease(Gumboro)ParainfluenzaPseudorabiesSwine PRRS virusTransmissible gastroenteritisVesicular stomatitis virusPorcine Epidemic Diarrhea Virus

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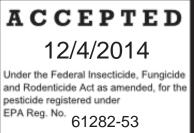
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Manufactured By: HACCO, Inc. 110 Hopkins Drive Randolph, WI 53956