

61282-53

12/16/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 16, 2008

Jennifer J. Seifert
Manager, Regulatory Affairs
HACCO, Inc.
110 Hopkins Drive
Randolph, WI 53956

Subject: Notification Application Per PR Notice 98-10
BioPhene Liquid Disinfectant
EPA Registration No. 61282-53
Application Date: November 21, 2008
Receipt Date: November 24, 2008

Dear Ms. Seifert:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification:

- Additional brand name: BioSentry@BioPhene™ Disinfectant


General Comment:

Based on a review of the material submitted, the following comment applies:

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions concerning this letter, you may contact me by telephone at (703) 308-6422 or by e-mail at heyward.adam@epa.gov or Lisa McKelvin by telephone at (703) 308-7496 or by email at mckelvin.lisa@epa.gov.

Sincerely,


Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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(A)	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460 Application for Pesticide:	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other Notification	OPP Identifier Number
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Section I

1. Company/Product Number 61282-53	2. EPA Chemical Manager Adam Heyward	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BioPhene Liquid Disinfectant	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) HACCO, Inc. 110 Hopkins Drive Randolph, WI 53956		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____
<input type="checkbox"/> Check if this is a new address		

Section II

<input type="checkbox"/> Amendment - Explain Below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below	<input type="checkbox"/> Other - explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II).
 NOTIFICATION OF Additional Brand Name: BioSentry® BioPhene™ Disinfectant

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) <u>C</u>
*Certification must be submitted.		If "Yes," Unit Package Wt. No. Per Container	If "Yes," Package Wt. No. Per Container

3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
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6. Manner In Which Label Is Affixed To Product Lithograph Other (_____)
 Paper Glued
 Stenciled

Section IV

1. **Contact Point** (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Jennifer J. Seifert	Title Manager, Regulatory Affairs	Telephone No. (include Area Code) (920) 326-2461
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<p style="text-align: center;">Certification</p> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.	6. Date Application Received (Stamp)
2. Signature 	3. Title Manager, Regulatory Affairs
4. Typed Name Jennifer J. Seifert	5. Date November 21 st , 2008

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Manufacturing Plant
110 Hopkins Drive
Randolph, WI 53956-1316
920 / 326-5141
920 / 326-5135
www.hacco.com

Registration Office
110 Hopkins Drive
Randolph, WI 53956-1316
920 / 326-5141
920 / 326-5135
www.hacco.com

November 21st, 2008

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Fed Ex: 8654 2248 4086

RE: BioPhene Liquid Disinfectant
EPA Reg. No. 61282-53

Gentlemen/Ladies:

Pursuant to PR-Notices 98-10, in regard to the subject product, we are hereby notifying the Agency of the following alternate brand name: BioSentry[®] BioPhene[™] Disinfectant.

Following is my statement as required by PR-Notice 98-10:

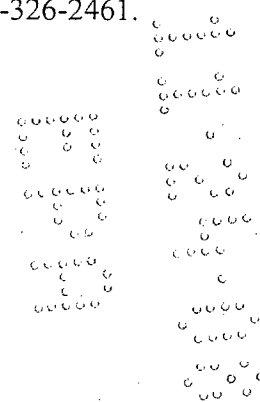
This notification is consistent with the provisions of PR-Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with terms of PR-Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Attached please find the completed application form marked for Notification, as well as a "before" and "after" label, with the alternate brand name clearly marked.

If you should have any questions regarding this matter, please contact me at 920-326-2461.

Sincerely,


Jennifer J. Seifert
Manager, Regulatory Affairs
HACCO, Inc.
jseifert@neogen.com



Enclosure(s): 2

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):

Applicators and other handlers must wear:

- Long-sleeved shirt and pants
- Socks plus shoes
- Goggles or face shield
- Chemical-resistant apron
- Chemical-resistant gloves (such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, PVC or viton ≥ 14 mils).

USER SAFETY REQUIREMENTS:

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS:

Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

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.

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.

<i>Alcaligenes faecalis</i>	<i>Aspergillus fumigatus</i>
<i>Brevibacter ammoniagenes</i>	<i>Brucella abortus</i>
<i>Candida albicans</i>	<i>Enterobacter aerogenes</i>
<i>Enterococcus faecium</i>	<i>Escherichia coli</i>
(<i>Streptococcus faecalis</i>)	
<i>Klebsiella pneumoniae</i>	<i>Mycoplasma gallisepticum</i>
<i>Mycoplasma iners</i>	<i>Pasteurella multocida</i>
<i>Pseudomonas aeruginosa</i>	<i>Salmonella choleraesuis</i>
<i>Salmonella enteritidis</i>	<i>Salmonella schottmuelleri</i>
<i>Shigella dysenteriae</i>	<i>Staphylococcus aureus</i>
<i>Streptococcus pyogenes</i>	<i>Trichophyton mentagrophytes</i>

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:

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

BEFORE LABEL

BioPhene Liquid Disinfectant

Disinfectant • Cleaner

* See Side Panels for Specific Claims

FOR INDUSTRIAL AND COMMERCIAL USE ONLY

* 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.....	7.92%
o-Benzyl-p-chlorophenol.....	9.97%
p-tert-Amylphenol.....	95.0%
INERT INGREDIENTS:	80.16%
TOTAL:	100.00%

EPA Reg. No. 61282-53

EPA Est. No. 10183-MI 01

**KEEP OUT OF REACH OF CHILDREN
DANGER**

SEE SIDE PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS

FIRST AID	
Have label with you 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.
If on skin or on clothing	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Remove and wash contaminated clothing before reuse.
If swallowed	Call a poison control center or doctor 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. 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 mouth-to-mouth, if possible.
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 1-651-523-0138 (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.	

NET WEIGHT: 1 gallon

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

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 feeding and watering equipment with detergent and rinse with potable water before reuse.

POULTRY HATCHERIES: BioPhene Liquid Disinfectant is effective for cleaning and disinfecting hatchery, 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 misting. Water temperatures from 75° F to 110° F (24° C to 44° C) are recommended on hatching eggs only. Do not apply on eggs that are to be consumed.

FOR FOG APPLICATIONS: Thoroughly ventilate entire enclosed area following application. This fog generated by the BioSentry® Fogger is very irritating to eyes, skin and mucous membranes. Do not enter, allow other persons to enter, house livestock, or use equipment in the treated area until ventilation is complete and any liquid has been absorbed, set, or dried. For entry into fogged areas before ventilation is complete and fog has completely dissipated, all persons must wear the personal protective equipment, including a full-face respirator, required for applicators and other handlers.

SANITIZING POULTRY HOUSES AND LIVESTOCK BUILDINGS USING BIOPHENE LIQUID DISINFECTANT THROUGH THE BIOSENTRY® FOGGER 185: After the house has been depopulated and cleaned as in (a) (b) (c) and (d) under "General Farm Disinfectant Uses," double check to be sure that all people, poultry, livestock and pets have vacated the building. Close all windows, doors, louvers, curtains, etc., making the house as closed and tight as possible. Mix one (1) part BioPhene Liquid Disinfectant with two (2) parts water in the reservoir of the BioSentry® Fogger 185. With the setting on maximum output, fog the treatment into the room or building to be sanitized. (Use a total of one (1) gallon (3.79 liters) of BioPhene Liquid Disinfectant for each 6000-8000 square feet of floor space. If the area is more than 25 feet high, use two (2) gallons (7.6 liters) per 6000-8000 square feet of floor space. In multi-story buildings, the application must be repeated for each floor that is to be sanitized.) The Fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the Fogger may be inserted through a suitable opening in the door or building. The opening should be just large enough to accommodate the nozzle. After fogging, the building should be kept closed for twenty-four hours. After twenty-four hours, the fog should have settled and the house can now be opened and aired. The house should be opened for a minimum of twenty-four to forty-eight hours before it is repopulated with poultry or livestock.

NOTE: If feeders and waterers were not removed from the premises during the treatment, or were not adequately covered to prevent contact with treatment, they should be washed with detergent and water before use for poultry or livestock.

SANITIZING HATCHERY ROOMS USING BIOSENTRY® FOGGER 185: room off so fog is confined to room to be treated. Mix one (1) part BioPhene Liquid Disinfectant to five (5) parts water (1.8 liters to 9.0 liters water) (1/2 gallon BioPhene Liquid Disinfectant to 2.5 gallons water). Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute for each 4,000 cubic feet of space in the room. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-2 hours in this environment.

INCUBATOR AND HATCHER FOGGING: Prepare a stock solution of six (6) ounces BioPhene Liquid Disinfectant to 122 ounces water (1.8 liters to 3.6 liters). Fog 3-8 ounces (88-236 ml) of this into setters and hatchers immediately after transfer. Repeat daily in setters and every 12 hours in hatchers.

NOTE: Discontinue hatcher treatments at least 24 hours prior to pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). It is also satisfactory to fog setters and hatchers with a 1/2 ounce per gallon (4 ml / liter) solution of BioPhene Liquid Disinfectant on an hourly or every other hour basis. If this is done, fog for 30-90 seconds once per hour or once every two hours. Fogging is to be used as an adjunct to acceptable manual cleaning and disinfecting of room and machine surfaces.

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

NOTIFICATION
Date Reviewed: 12-16-98
Reviewed By: [Signature]

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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 soles from boots.

FOR HEALTH-CARE FACILITIES: 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.

FOR SCHOOLS, MOTELS, INSTITUTIONAL AND INDUSTRIAL 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.

For Container Sizes 1 Gallon or Less:

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

For Container Sizes Greater than 1 Gallon:

PESTICIDE STORAGE:

Do not store on side. Avoid creasing or impacting of side walls.

PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinseate 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:

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.

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.

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. 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. **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.**

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. 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 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 of liability, which may not be modified except by written agreement signed by a duly authorized representative of Manufacturer.

For medical emergencies or questions involving this product,
call 1.800.498.5753.

