

61282-53

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

FEB 26 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Jennifer Siefert
HACCO, Inc.
110 Hopkins Drive
Randolph, WI 53956

Subject: **BioPhene Liquid Disinfectant**
EPA Registration No.: 61282-53
Application Date: February 11, 2009
Receipt Date: February 13, 2009

Dear Ms. Siefert:

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

Proposed Notification:

Revised Storage and Disposal Statements

General Comment:

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

A copy of the notification is accepted and has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-8583 or by e-mail at mitchell.emily@epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at grigsby.stacey@epa.gov during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Emily Mitchell
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

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

Section I

1. Company/Product Number 61282-53	2. EPA Chemical Manager Adam Heyward	3. Proposed Classification <input checked="" 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 <input type="checkbox"/> Check if this is a new address	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 _____	

Section II

Amendment - Explain Below Final printed labels in response to Agency letter dated _____
 Resubmission in response to Agency letter dated _____ "Me Too" Application
 Notification - Explain below Other - explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II).
 NOTIFICATION of Revised Storage and Disposal statements. Pursuant to PR-Notice 2007-04, for the product: BioPhene Liquid Disinfectant, EPA Reg. No. 61282-53.

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No <small>*Certification must be submitted.</small>	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," Unit Package Wt. No. Per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," Package Wt. No. Per Container	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>
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

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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Certification
 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.

2. Signature 	3. Title Manager, Regulatory Affairs	6. Date Application Received (Stamped)
4. Typed Name Jennifer J. Seifert	5. Date 2/1/09	



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

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February 11th, 2009

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

Fed Ex: 8671 4551 1755

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

Gentlemen/Ladies:

Pursuant to PR-Notices 2007-04, in regard to the subject product, we are hereby notifying the Agency of the revision to the Storage and Disposal text.

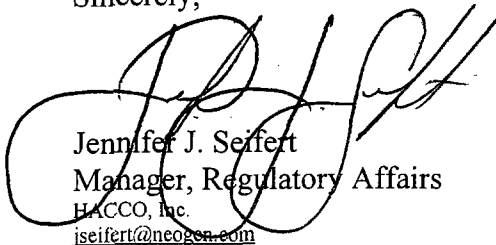
Following is my statement as required by PR-Notice 2007-04:

Notification of label change per PR Notice 2007-04. This notification is consistent with the guidance in PR Notice 2007-04 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. 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 statements to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156, 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

BioPhene™ Liquid Disinfectant

Disinfectant • Cleaner

FOR INDUSTRIAL AND COMMERCIAL USE ONLY

- * Proven Effective as a One-Step Cleaner-Disinfectant in the Presence of 5% Organic Serum for Poultry, Swine, and 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.....	1.95%
INERT INGREDIENTS.....	80.16%
TOTAL INGREDIENTS.....	100.00%

EPA Reg. No. 61282-53

EPA Est. No. 10183-MI-01

KEEP OUT OF REACH OF CHILDREN DANGER

FIRST AID

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 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 1-651-523-0318 (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.

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, BioSentry® BioPhene™ Disinfectant is an effective disinfectant in 400 ppm hard water and 5% serum against the following bacteria and fungi.

<i>Alcaligenes faecalis</i>	<i>Aspergillus fumigatus</i>	<i>Brevibacter ammoniogenes</i>
<i>Brucella abortus</i>	<i>Candida albicans</i>	<i>Enterobacter aerogenes</i>
<i>Enterococcus faecium (Streptococcus faecalis)</i>		<i>Escherichia coli</i>
<i>Klebsiella pneumoniae</i>	<i>Mycoplasma gallisepticum</i>	<i>Mycoplasma thers</i>
<i>Pasteurella multocida</i>	<i>Pseudomonas aeruginosa</i>	<i>Salmonella choleraesuis</i>
<i>Salmonella enteritidis</i>	<i>Salmonella schottmulleri</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, BioSentry® BioPhene™ Disinfectant is effective at 1:256 in 400 ppm 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

DIRECTIONS FOR USE

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

BioSentry® BioPhene™ 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 ½ ounce of BioSentry® BioPhene™ 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 1 ½ 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 ½ ounce per gallon. Allow to dry without wiping. Reapply as new growth appears.

GENERAL FARM DISINFECTANT USES:

(¼ ounce per gallon) (4 ml/liter)

- Remove all animals, poultry and feed from premises, trucks and enclosures.
- 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.
- Empty all troughs, racks, and other feeding and watering appliances.
- Thoroughly clean all surfaces with soap or detergent and rinse with water.
- Saturate all surfaces with the recommended solution for a period of 10 minutes.
- 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.
- 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.
- Thoroughly scrub treated feeding and watering equipment with detergent and rinse with potable water before reuse.

POULTRY HATCHERIES: BioSentry® BioPhene™ 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 BioSentry® BioPhene™ Disinfectant diluted ½ 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 ½ ounce per gallon (4 ml/liter) of BioSentry® BioPhene™ 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.

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 BIOSENTRY® BIOPHENE™ 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 1 part BioSentry® BioPhene™ Disinfectant with two parts water in the reservoir of the BioSentry® Fogger. With the setting on maximum output, fog the treatment into the room or building to be sanitized. (Use a total of 1 gallon (3.79 liters) of BioSentry® BioPhene™ Disinfectant for each 6000-8000 square feet of floor space. If the area is more than 25 feet high, use 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: Close room off so fog is confined to room to be treated. Mix one (1) part BioSentry® BioPhene™ Disinfectant to five (5) parts water (1.8 liters to 9.0 liters

water) (¼ gallon BioSentry® BioPhene™ Disinfectant) suitable opening into the room. With the sett space in the room. Do not allow people to be settled or exhausted. Normally this is 1-2 hours

INCUBATOR AND HATCHER FOGGING: To 122 ounces water (1.8 liters to 3.6 liters). Transfer. Repeat daily in setters and every 12 hours

NOTE: Discontinue hatcher treatments at 12 hours. Do not breathe this fog and do not enter machines unless satisfactory to fog setters and hatchers will disinfect on an hourly or every other hour hours. Fogging is to be used as an adjunct to a

VEAL, CALVING, HOG, CATTLE AND DISINFECTANT: Use 1 ounce per gal becomes visibly soiled. Use a nylon brush to clean

FARM BOOT BATH: Use 1 ounce per gal becomes visibly soiled. Use a nylon brush to clean

FOR HEALTH-CARE FACILITIES: At ½ an effective cleaner and germicide for floors, operating rooms, emergency rooms, patient rooms

FOR SCHOOLS, MOTELS, INSTITUTIONS: At ½ an effective cleaner and germicide for floors, operating rooms, emergency rooms, patient rooms

FOR SPRAY APPLICATIONS: Following others to enter treated area until sprays have dried

APPLICATION RESTRICTIONS: Do not directly or through drift. Only protected hand

STORAGE

Do not contain

For Container Sizes 1 Gallon or Less:

Store in original container in areas inaccessible Do not reuse empty container. Discard in trash

For Container Sizes Greater than 1 Gallon:

Do not store on side. Avoid creasing or impact

PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Imp

Federal Law. If these wastes cannot be disposed

Environmental Control Agency, or the Hazard

CONTAINER DISPOSAL:

Triple rinse (or equivalent). Then offer for re

by incineration, or, if allowed by State and loc

For non-

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Code (NE.NT.) NE.NO.

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