

71654-17

02/21/2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

February 21, 2007

Wende L. Faulk  
Regulatory and Product Stewardship Coordinator  
DuPont Chemical Solutions Enterprise  
P.O. Box 80402  
Wilmington, DE 19880-0402

Subject: BioPhene Liquid Disinfectant  
EPA Registration No.: 71654-17  
Application Date: February 2, 2007  
Receipt Date: February 7, 2007

Dear Ms. Faulk,

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

**Proposed Notification**

- Add emergency hotline text.
- Add EPA registration number

**General Comments**

Based on a review of the material submitted, the following comments apply:

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

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422.

Sincerely,

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

CONCURRENCES							
YMBOL	7510P						
JRNAME	Graw						
ATE	2/21/07						



DuPont Chemical Solutions Enterprise

DELIVERED BY COURIER

February 2, 2007

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

**SUBJECT: BioPhene Liquid Disinfectant : EPA Registration # 71654-17**  
**Notification of Minor Label Changes Pursuant to PR Notice 98-10**

Dear Sir or Madam:

In accordance with PR Notice 98-10, I am notifying the Agency of minor label changes being proposed for BioPhene Liquid Disinfectant (EPA Reg No. 71654-17). The label changes being made are in response to recent industry feedback regarding recent EPA interpretation of 40 CFR Part 156.10(c). The manufacturer has been re-qualified to more accurately reflect the nature of the production site.

Please find the following enclosed documents supporting this notification:

- Application for Pesticide Registration (EPA form 8570-1) – dated February 2, 2007
- 5 copies of the revised label – one copy with changes highlighted

This request 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 the product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-19 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.

Feel free to contact me by phone at 302-695-1629 or by email at [wende.l.faulk@usa.dupont.com](mailto:wende.l.faulk@usa.dupont.com) if you have any questions.

Sincerely,

Wende L. Faulk  
Regulatory & Product Stewardship Coordinator  
E.I. du Pont de Nemours and Company

*attachments*

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 05-31-98



EPA

United States  
Environmental Protection Agency  
Washington, DC 20460

- Registration
- Amendment
- Other: NOTIFICATION

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number <b>71654-17</b>	2. EPA Product Manager <b>Adam Heyward</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Bio-Phene Liquid Disinfectant</b>	PM# <b>Team 34</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>E.I. DuPont de Nemours and Company DuPont Chemical Solutions Enterprise, P.O. Box 80402 DuPont Experimental Station, E402-3231B Wilmington, DE 19880-0402 Attn: Wende Faulk</b> <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

<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 checked="" 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 minor label changes in accordance with industry guidance regarding recent Agency interpretation of 40 CFR Part 156.10(c)

**Notification of MINOR LABEL CHANGES in Accordance With 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 changes have been made to the labeling or the confidential statement of formula of 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 the 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.

Signature: Wende Faulk Date: February 3, 2007

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
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	Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) <input type="checkbox"/>		
*Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) 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 <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application;		
Name <b>Wende Faulk</b>	Title <b>Regulatory &amp; Product Stewardship Coordinator</b>	Telephone No. (Include Area Code) <b>(302) 693-1629</b>
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.		6. Date Application Received <b>(Stamped)</b>
2. Signature <u>Wende Faulk</u>		
3. Title <b>Regulatory &amp; Product Stewardship Coordinator</b>		
4. Typed Name <b>Wende Faulk</b>		5. Date <b>February 2, 2007</b>

(front panel)

# BioSentry<sup>®</sup> BioPhene<sup>™</sup> 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.....	7.92%
o-Benzyl-p-chlorophenol.....	9.97%
p-tert-Amylphenol .....	1.95%
<b>INERT INGREDIENTS .....</b>	<b>80.16%</b>
<b>TOTAL INGREDIENTS .....</b>	<b>100.00%</b>

EPA REG NO 71654-17

EPA EST NO xxxxx-xx-xx

## KEEP OUT OF REACH OF CHILDREN DANGER

See (left) (side) (right) (back) panel for Precautionary Statements

FOR INDUSTRIAL AND COMMERCIAL USE ONLY

NET CONTENTS: (as indicated on container)

### 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 by 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 1-800-441-3637 (US & Canada) or 1-302-774-1000 (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.

(side / middle panel)

**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  $\geq 14$  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.

*(Note to reviewer: If container is greater than one gallon, the following environmental hazards statements will be used:)*

**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.

*(Note to reviewer: If the container size is one gallon or less, the following storage and disposal statements will be used:)*

**STORAGE AND DISPOSAL**

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.

*(Note to reviewer: If container is greater than one gallon, the following storage and disposal statements will be used:)*

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**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 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:**

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.

**BACTERIA & FUNGI:** Using AOAC Use dilution test, Bio-Phene is an effective disinfectant in 400 ppm 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 (Streptococcus faecalis)
- Escherichia coli
- Klebsiella pneumoniae
- Mycoplasma gallisepticum
- Mycoplasma iners
- Pasteurella multocida
- Pseudomonas aeruginosa
- Salmonella choleraesuis
- Salmonella enteritidis
- Salmonella schottmuelleri
- Shigella dysenteriae
- Staphylococcus aureus
- Streptococcus pyogenes
- Trichophyton mentagrophytes

**VIRUSES:** Using accepted virus propagation and hard surface test methods, Bio-Phene 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.

Bio-Phene 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 ½ ounce of Bio-Phene 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 1½ 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:**

(½ 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:** Bio-Phene Liquid Disinfectant is effective for cleaning and disinfecting hatching, setters, buggies, trays, racks, equipment, utensils and other environmental surfaces in avian hatcheries. After initial cleaning and disinfecting with Bio-Phene diluted ½ ounce per gallon (4 ml/ liter), rinse and reapply a fresh disinfecting solution. Do not rinse again. One step cleaning and disinfecting is not recommended in hatcheries.

**SANITIZING HATCHING EGGS:** Use ½ ounce per gallon (4 ml/ liter) of Bio-Phene 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 BIO-PHENE 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 Bio-Phene 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 Bio-Phene 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 waters 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 Bio-Phene to five (5) parts water (1.8 liters to 9.0 liters of water) (½ gallon Bio-Phene 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 6 ounces Bio-Phene to 122 ounces water (1.8 liters to 3.6 liter). 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 ½ ounce per gallon (4 ml/ liter) solution of Bio-Phene 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 ½ ounce per gallon (4 ml/ liter) of Bio-Phene 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 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:** At ½ ounce per gallon of water (4 ml/ liter), Bio-Phene 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 ½ ounce per gallon of water (4 ml/ liter), Bio-Phene 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.

MANUFACTURED FOR:

E.I. du Pont de Nemours and Company  
P.O. Box 80023  
Wilmington DE 19880-0023

Questions? Call 1 800-441-7515  
(outside U.S. 302-774-1000)

*(insert trademark statement)*

*(insert copyright statement)*

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