## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

71654-19

31712007



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY Washington, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MAR - 7 2007

Wende Faulk Regulatory & Product Stewardship Coordinator E.I DuPont de Nemours and Company DuPont Chemical Solutions Enterprise P.O. Box 80402 DuPont Experimental Station, E402-3231B Wilmington, DE 19880

Subject:

BioSentry 904

EPA Reg. No. 71654-19

Application Dated: Feb 02, 2007 Receipt Date: Feb 07, 2007

### Dear Wende Faulk

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9. is acceptable.

### **Proposed Notification**

Making Minor Change to label

#### Comments

Based on a review of the material submitted, the following comments apply: This application for notification to make minor changes to the label is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely.

Velma Noble

Product Manager (31)

Regulatory Management Branch1 Antimicrobial Division (7510c)0

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CONCURRENCES						
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SURNAME						
DATE 31-116		***************************************				
EPA Form 1320-1A (1/90)	Printed on Remoded	ane	OFFICI	AL FILE CODY		

l Form 1320-1A (1/90)

Printed on Recycled Power

Please read instructions on reverse before completing form.		Form Approved, OMB No. 2070	0060, Approval expires 05-31-98			
United States		☐ Registration	OPP Identifier Number			
EPA Environmental Protection	n Agency					
	• •	☐ Amendment	)			
Washington, DC 204	-60	<b>◯</b> Other: NOTIFICATIO	N ]			
Application for Pesticide - Section I						
Company/Product Number	2. EPA Product	Manager	Proposed Classification			
71654-19	Velma Noble					
4. Company/Product (Name)	PM#		None Restricted			
BioSentry 904	Team 23					
Name and Address of Applicant (Include ZIP Code)		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)				
E.I. DuPont de Nemours and Company	(b)(l), my pro	(b)(l), my product is similar or identical in composition and labeling				
DuPont Chemical Solutions Enterprise, P.O. Box 80402	to:					
DuPont Experimental Station, E402-3231B	EPA Reg. No.					
Wilmington, DE 19880-0402						
Attn: Wende Faulk Product Name						
Check if this is a new address	<u> </u>					
	Section - II					
Amendment – Explain below.	F	inal printed labels in response to	Agency letter dated			
Resubmission in response to Agency letter dated	,,	Me Too" Application				
Notification - Explain below.	<u>-</u>	Other - Explain below				
Explanation: Use additional page(s) if necessary. (For Section						
Notification of minor label changes in accordance with industry guidance regarding recent Agency interpretation of 40 CFR Part 156.10(c)						
			· · · · · · · · · · · · · · · · · · ·			
		cordance With PR Notice 98-10				
This notification is consistent with the provisions of PR Notice 98-10 and confidential statement of formula of this product. I understand that it is a						
understand that if this notification is not consistent with the terms of PR						
subject to enforcement action and penalties under sections 12 and 14 of I		•	•			
I INTRODUCE	+ 2/2	11/112 7 7/117				
Signature: 12/2 Maris 2, 700 7						
	Section - III					
Material This Product Will Be Packaged In:  Only Registrat Packaged  Only Registrat Packaged  Only Registrat Packaged  Only Registrat Packaged  Only Registration  Only Registratio	Mot	or Calubia Dagharian	2. Tuno of Containing			
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No No		No	Plastic			
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be submitted			Other (Specifiy)			
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DuPont Chemical Solutions Enterprise P. O. Box 80402 Wilmington, DE 19880-0402



**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: BioSentry 904: EPA Registration # 71654-19

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 BioSentry 904 (EPA Reg No. 71654-19). 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 if you have any questions.

Sincerely,

Wende L. Faulk

Regulatory & Product Stewardship Coordinator

E.I. du Pont de Nemours and Company

attachments

## BioSentry® 904

- · Poultry hatchery disinfectant
- · Farm premise disinfectant
- · Veterinary and animal care disinfectant
- For chicken, turkey, duck, quail, ostrich and other avian hatcheries
- · For poultry, swine and livestock premises
- For veterinary, laboratory animal, kennel and animal breeder facilities
- Effective in 400-ppm hard water as (caco<sub>3</sub>)
- · Disinfects in 5% organic soil load

#### **BACTERICIDE, FUNGICIDE, VIRUCIDE\***

\*See (left) (side) (right) (back) panel for specific claims

#### **ACTIVE INGREDIENTS:**

Didecyl dimethyl ammonium chloride	9.2%
Alkyl (C <sub>12</sub> , 61%; C <sub>14</sub> , 23%; C <sub>16</sub> , 11%; C <sub>18</sub> . 2.5%	; C <sub>8</sub>
& C <sub>10</sub> , 2.5%) dimethyl benzyl ammoniu	m
chloride	9.2%
Alkyl (C <sub>12</sub> ; 40%; C <sub>14</sub> , 50%; C <sub>16</sub> , 10%) dimethyl	
benzyl ammonium chloride	4.6%
bis-n-tributyltin oxide	1.0%
INERT INGREDIENTS:	<u>76.0%</u>
TOTAL INGREDIENTS:	

EPA Reg. No. 71654-19

EPA Est. No. xxxxx-xx-xx

# 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.

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.

(side pancl)

### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes severe eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and rubber gloves when handling. Harmful or fatal if swallowed or inhaled. Avoid breathing vapors or spray mist. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

**PHYSICAL AND CHEMICAL HAZARDS**: Do not use or store near heat or open flame.

(Note to reviewer: If container is greater than one gallon, the following environmental hazards statement 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.

(side panel)

#### BROAD SPECTRUM GERMICIDAL ACTION IN HARD WATER AND UNDER SOIL LOAD CONDITIONS: At 1/2

ounce per gallon (1:256) in official AOAC Use Dilution and Fungicidal Tests, BioSentry® 904 is effective in water up to 400 ppm hardness (as CaCO<sub>3</sub>) and an organic soil load of 5% serum against the following organisms:

#### **BACTERIA**

Actinobacillus pleuropneumoniae ATCC 27088

Actinomyces pyogenes ATCC 19411

Alcaligenes faecalis ATCC 8748

Bordetella avium ATCC 35086

Bordetella bronchiseptica ATCC 19395

Corynebacterium pseudotuberculosis ATCC 19410

Enterobacter aerogenes ATCC 63809

Enterococcus faecium ATCC 6569 (Streptococcus faecalis)

Escherichia coli ATCC 11229

Klebsiella pneumoniae ATCC 4352

Mycoplasma hypopneumoniae ATCC 25934

Mycoplasma gallinarum ATCC 19708

Mycopiasma gallisepticum ATCC 15302

Mycoplasma iners ATCC 19705

Pasteurella multocida ATCC 7707

Proteus mirabilis ATCC 25933

Proteus morganii ATCC 25830

Pseudomonas aeruginosa ATCC 15442

Rhodococcus equi ATCC 6939

Staphylococcus aureus ATCC 6538

Salmonella choleraesuis ATCC 10708

Salmonella enteriditis ATCC 4931 Salmonella gallinarum ATCC 9184

Salmonella pullorum ATCC 9120

Salmonella typnosa ATCC 6539 Serratia marcescens ATCC 264

Shigella dysenteriae ATCC 13313

Shigella sonnei ATCC 29930

Streptococcus equi var. equi ATCC 33398

Streptococcus agalactiae ATCC 27916

Streptococcus pyogenes ATCC 9547

Streptococcus equi var. zooepidermicus ATCC 43079

#### **FUNGI**

Aspergillus fumigatus ATCC 10894

Candida albicans ATCC 18804

Trichophyton mentagrophytes var. interdigitale ATCC 9533

#### VIRUSES

Using accepted virus propagation and hard surface test methods, BioSentry® 904 is effective at 1:256 in 400 ppm hard water and 5% serum against the following viruses

Avian influenza ATCC VR-798

Avian laryngotracheitis ATCC VR-783

Canine distemper Onderstepoort strain

Canine herpesvirus ATCC VR-552

Canine parvovirus ATCC VR-953

Equine herpesvirus ATCC VR-700

Equine influenza A ATCC VR-297

Feline infectious peritonitis Strain DF-2

Infectious bronchitis ATCC VR-22

Infectious bursal disease (Gumboro) ATCC VR-478

Newcastle's disease ATCC VR-109

Parainfluenza ATCC VR-281

Porcine parvovirus ATCC VR-742

Pseudorabies ATCC VR-135

Swine PRRS virus Reference Strain, NVSL

Transmissible gastroenteritis ATCC VR-763

Vesicular stomatitis virus, Indiana

BioSentry® 904 is a complete, chemically balanced disinfectant providing clear use solutions even in hard water – is a residual bacteriostat and inhibits bacterial growth on moist surfaces – contains rust and corrosion inhibitors – deodorizes by killing most microorganisms that cause offensive odors – kills a broad range of gramnegative and gram-positive bacteria, fungi and viruses associated with the avian hatching industry, poultry, swine and livestock premises, laboratory animal facilities and kennels. (See antimicrobial efficacy chart on back (side) label panel). Contains sequestering agents, to prevent the precipitation of minerals and metals from hard water.

#### **DIRECTIONS FOR USE**

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

# DIRECTIONS FOR USE ON POUTLRY, SWINE AND LIVESTOCK FARMS GENERAL FARM DISINFECTANT USES:

(1/2 ounce per gallon)

- (a) Remove all livestock and feeds from premises, trucks, coops or crates to be treated.
- (b) Remove all litter, bedding and manure from floors, walls and surfaces of facilities traversed or occupied by animals.
- (c) Empty all feeding devices and watering appliances.
- (d) Clean all surfaces with water or water and a compatible detergent.
- (e) Saturate all surfaces with this product diluted at ½ ounce per gallon of water using a brush, cloth, mop or mechanical spraying device. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used in removing litter and manure. Treated surfaces must remain moist for at least 10 minutes for proper germicidal action.
- (f) Ventilate buildings, trucks, coops and other closed spaces. Do not house livestock or use equipment until treatment has thoroughly dried.
- (g) Thoroughly scrub treated feeding and watering equipment with detergent and rinse with potable water before reuse.

FOR DISINFECTING PRECLEANED SURFACES: Use BioSentry® 904 to disinfect precleaned surfaces including hatchers, setters, trays, racks, egg flats, walls, floors, ceilings and other surfaces in the hatchery environment. It is also excellent for chickboxes, egg cases, vans and trash containers. Preclean the surface to be disinfected with BioSentry® 453 or another compatible BioSentry hatchery cleaner. Rinse and if possible let surfaces dry. Then, apply BioSentry® 904 at ½ ounce per gallon by immersion, by flowing solution over treated surfaces, by use of a soft coarse spray, or with a clean mop, cloth or through a foaming apparatus. Thoroughly wet surfaces. Surfaces should remain moist for 10 minutes for complete disinfection. Do not rinse. Leave treatment on treated

surfaces to maintain a bacteriostatic effect on moist surfaces.

**NOTE**: Do not spray BioSentry® 904 disinfecting solutions unless workers are protected from breathing the spray mist.

DISINFECTING CHICK VANS, EGG TRUCKS, HATCHERY AND FARM VEHICLES: Clean and rinse vehicles and disinfect with ½ ounce BioSentry® 904 per gallon. If desired, rinse after 10 minutes of contact or leave unrinsed.

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 of BioSentry® 904. Take care to avoid disinfectant use solution contact with animals, feed, feed equipment, water or watering devices. If spray contacts feeders or waterers, scrub them and rinse well with potable water before they are reused.

**BOOT BATH:** Use 1 oz. per gallon in boot baths. Change solution daily and anytime it becomes visibly soiled. Use a nylon bristled brush to clean soils from boots.

SANITIZING HATCHERY ROOMS USING THE BioSentry® FOGGER 185 OR agMISTER: Close room off so fog is confined to room to be treated. Mix one (1) part BioSentry® 904 to five (5) parts water (1/2 gallon BioSentry® 904 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 with the BioSentry® Fogger 185. If using the agMister, fog for 3 minutes 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 1-4 hours in this environment.

NOTE: The fog generated by the BioSentry® Fogger 185 and the agMister is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves and pants.

**SANITIZING INCUBATORS AND HATCHERS BY FOGGING**: Prepare a stock colution of 6 radial ounces BioSentry® 904 to 122 ounces water. Fog 3-8 ounces of this into setters and hatchers immediately after transfer.

Repeat daily in setters and every 12 hours into hatchers. Discontinue hatcher treatments approximately 24 hours before 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). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. Contact your BioSentry Technical Representative if you need assistance.

It is also satisfactory to fog setters and hatchers with a  $\frac{1}{2}$  ounce per gallon solution of BioSentry® 904. If this is done, fog for 30-90 seconds once per hour or once every two hours. Contact your BioSentry Technical Representative for assistance.

SANITIZING POULTRY HOUSES AND LIVESTOCK BUILDINGS USING BioSentry® 904 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 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 BioSentry® 904 with two (2) parts water in the reservoir of the BioSentry® Fogger 185 or agMister. With the setting on maximum output, fog the treatment into the room or building to be sanitized. Use a total of one (1) gallon of BioSentry® 904 for each 6000-8000 square feet of floor space. If the area is more than 25 feet high, use two (2) gallons 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 hours before it is repopulated with poultry or livestock.

NOTE: The fog generated by the BioSentry® Fogger 185 and the agMister is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 2-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves and pants. If feeders and waterers were not removed from the premise during 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.

Do not use BioSentry® 904 on vaccination equipment, needles or diluent bottles as the residual germicide may render the vaccines ineffective. BioSentry® 904 should

not be mixed with other cleaning or disinfecting compounds or products.

DIRECTIONS FOR USE IN VETERINARY CLINICS, ANIMAL CARE FACILITIES, ANIMAL RESEARCH CENTERS, ANIMAL BREEDING FACILITIES, KENNELS AND ANIMAL QUARANTINE AREAS. BioSentry® 904 is a one-step germicide, fungicide, soapless cleaner and deodorant effective in the presence or organic soil (5% serum). It is non-selective and when used as directed, will not harm tile, terrazzo, resilient flooring, concrete, painted or varnished wood, glass or metals.

For cleaning and disinfecting the following hard nonporous surfaces: equipment, utensils, instruments, cages, kennels, stables, stalls and catteries. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals.

Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use solution of ½ ounce per gallon of water (or equivalent dilution) for a period of 10 minutes. Apply by immersion, flushing solution over treated surfaces or with a mop, sponge, cloth or bowl mop to thoroughly wet surfaces. To clean badly soiled areas, use up to 1½ ounce per gallon of water. To control mold and mildew growth on previously cleaned, hard nonporous surfaces, use ½ ounce per gallon. Allow to dry without wiping. Reapply as new growth appears. Prepare fresh solutions daily or when solution becomes diluted or soiled.

Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers and other equipment that dispenses food or water with soap or detergent, and rinse with potable water before reuse.

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)