

4170-101

12/29/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



**Office of Pesticide Programs**

DEC 29 2009

Betco Corporation  
1001 Brown Avenue  
Toledo, Ohio 43607

Attention: Candice Ruston

**Subject: OxyFect H**

EPA Registration No. 4170-101

Notification Dated December 8, 2009

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9).

**Proposed Notification**

- To Add H1N1 Claims

**General Comment**

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

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

Please note that your "Storage and Disposal" language must be revised to comply with the "Container Rule" per PR Notice 2007-4. Based on this Notice, the language must incorporate residue removal instructions that are comparable to the container type.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,

Marshall Swindell  
Product Manager (33)  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

|  |   |  |
|--|---|--|
| 1. Company/Product Number<br>4170-101  | 2. EPA Product Manager<br>Marshall Swindell   | 3. Proposed Classification<br><input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name)<br>Betco Corporation OxyFect H   | PM#<br>33   |  |
| 5. Name and Address of Applicant (Include ZIP Code)<br>Betco Corporation<br>1001 Brown Avenue<br>Toledo, Ohio 43607<br><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:<br>EPA Reg. No. 4170-101<br>Product Name OxyFect H |  |

## 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.)

Additional Influenza Statements added to page 3 of the master label, per US EPA Guidance concerning "Pandemic Influenza".

## Section - III

|   |  |   |                   |   |                   |
|---|--|---|-------------------|---|-------------------|
| 1. Material This Product Will Be Packaged In:   |  |   |                   | 2. Type of Container  |                   |
| Child-Resistant Packaging<br><input checked="" type="checkbox"/> Yes*<br><input type="checkbox"/> No                    | Unit Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No | Water Soluble Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No                 |                   | <input checked="" type="checkbox"/> Metal<br><input type="checkbox"/> Plastic<br><input type="checkbox"/> Glass<br><input type="checkbox"/> Paper<br><input type="checkbox"/> Other (Specify) _____ |                   |
| * Certification must be submitted   |  | If "Yes" Unit Packaging wgt.  | No. per container | If "Yes" Package wgt.   | No. per container |
| 3. Location of Net Contents Information<br><input checked="" type="checkbox"/> Label <input type="checkbox"/> Container |  | 4. Size(s) Retail Container<br>1Gal, 2L, 5 Gal  |                   | 5. Location of Label Directions<br><input checked="" type="checkbox"/> On Label<br><input type="checkbox"/> On Labeling accompanying product  |                   |
| 6. Manner in Which Label is Affixed to Product<br>Silk Screen, Label  |  | <input type="checkbox"/> Lithograph<br><input type="checkbox"/> Paper glued<br><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<br>Candice Rushton  |  | Title<br>Regulatory Affairs Manager                 |   |
|  |  | Telephone No. (Include Area Code)<br>(419) 725-3823 |   |
| <b>Certification</b><br>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. |  |   | 8. Date Application Received<br>(Stamped)<br> |
| 2. Signature<br>   |  | 3. Title<br>Regulatory Affairs Manager              |   |
| 4. Typed Name<br>Candice Rushton   |  | 5. Date<br>12/08/2009                               |   |
|  |  |   |   |



**INNOVATIVE  
CLEANING TECHNOLOGIES**

Betco Corporation  
1001 Brown Avenue  
P.O. Box 3127  
Toledo, Ohio 43607-0127  
419-241-2156  
800-333-2156

Customer Service:  
888-GO BETCO  
(888-462-3826)  
Fax: 800-445-5056  
email@betco.com  
www.betco.com

December 8, 2009

Mr. Marshall Swindell (PM33)  
Front End Processing (AMEND)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave. NW  
Washington, D.C. 20460

**RE: OxyFect H EPA Registration 4170-101  
Notification: Additional Influenza A Statements to Include "Pandemic Flu"  
NO PRIA FEE IS REQUIRED FOR THIS ACTION**

Dear Mr. Swindell:

As the product OxyFect H has been shown to be effective against Influenza A Virus, Betco Corporation is requesting that the following additional statements be added to the product label:

***"Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product (Product Name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu)."***

***"This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus."***

***"This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu)."***

***"Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)."***

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 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.

Sincerely,

Candice Rushton  
Regulatory Affairs Manager

Master label OxyFect H Peroxide Cleaner Disinfectant -Cleaner  
(Items in Paranthesis indicate optional marketing text)



## OxyFECT-H Peroxide Disinfectant Cleaner

(\*Virucidal) (Hospital Disinfectant)

(Cleans), (Deodorizes), (Disinfects)

For (Commercial), (Industrial), (Hospital), (Institutional) Use

### ACTIVE INGREDIENT:

|                                 |         |
|---------------------------------|---------|
| Hydrogen Peroxide .....         | 6.88%   |
| INERT (OTHER) INGREDIENTS ..... | 93.12 % |
| TOTAL:.....                     | 100.00% |

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See (side)(back)(left)(right) panel for additional precautionary statements and first aid.

### FIRST AID:

**IF IN EYES:** Hold eye open. Rinse 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 immediately for treatment advice.

**IF ON SKIN OR ON CLOTHING:** Take off contaminated clothing immediately. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

**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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF INHALED:** Move victim 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 for further treatment advice.

**Have the product container or label with you when calling a poison control center or doctor or going for treatment.**

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

EPA Est. No. 4170-OH-1

EPA Reg. No. 4170-101

**Net Contents:**

**Disinfectant :** At a dilution of 6.5 oz.per gallon of water (1:20), 200 ppm hard water in the presence of 5% organic soil load with a 10 minute contact time, this product (Kills) (is effective against):

**(Bacteria):**

*Pseudomonas aeruginosa* (ATCC 15442),  
*Staphylococcus aureus* (ATCC 6538),  
*Salmonella enterica* (ATCC10708).

*Acinetobacter baumannii* (ATCC 19606)

Community Acquired Methicillin Resistant *Staphylococcus aureus* (CA-MRSA)  
(NARSA) (NRS123) (USA 400)

*Enterococcus faecalis* –Vancomycin Resistant (VRE) (ATCC 51575)

*Eschericia Coli* O157:H7 (ATCC 35150)

*Klebsiella pneumoniae* (ATCC 4352)

*Serratia marcescens* (ATCC 14756)

*Shigella sonnei* (ATCC 25931)

*Staphylococcus aureus*- Methicillin Resistant (MRSA)

*Streptococcus pneumoniae* (ATCC 6303)

**(Antibiotic Resistant Bacteria):**

Community Acquired Methicillin Resistant *Staphylococcus aureus* (CA-MRSA)  
(NARSA) (NRS123) (USA 400)

*Enterococcus faecalis* –Vancomycin Resistant (VRE) (ATCC 51575)

*Staphylococcus aureus*- Methicillin Resistant (MRSA)

**(Fungus/ Mold):**

*Aspergillus niger* (ATCC 6275)

**(\*Viruses)**

\*Hepatitis B Virus (DHBV) (HBV)

\*Herpes Simplex Virus Type 2 (ATCC VR-734)

\*Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS)

6/11

\*Influenza Type A (ATCC VR-100)

\*Respiratory Syncytial Virus

\*Rotavirus (Strain WA)

*("Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product (OxyFect H) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).")*

*("This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.")*

*("This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).")*

*("Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).")*

**This product can be used as a disinfectant in the following areas:**

Bathrooms  
Kitchens  
Day Care Centers  
Nurseries  
Athletic Facilities  
Airports  
Cruise Ships  
Casinos  
Office Buildings  
Colleges  
Correctional Facilities  
Dressing Rooms  
Exercise Facilities  
Factories  
Food service establishments (restaurants)  
Gyms  
Hotels  
Institutional Facilities  
Institutions  
Locker Rooms  
Motels  
Correctional Facilities  
Public Facilities  
Public Restrooms  
Retail facilities  
Schools  
Showers and Bath areas  
Boats  
Buses

Trailers  
Universities  
Warehouses

**This product can be used in the following hospital/ healthcare settings :**

Dental Offices  
Health Care Facilities  
Hospitals  
Medical Offices  
Nursing Homes

**This product can be used on the following washable, hard, inanimate, non-porous surfaces:**

Aluminum  
Bathroom fixtures – **NOTE: DO NOT USE ON BRASS**  
Bathtubs  
Cabinets  
Ceilings  
Chairs  
Chrome  
Counters (Countertops)  
Desks  
Doorknobs – **NOTE: DO NOT USE ON BRASS**  
Faucets – **NOTE: DO NOT USE ON BRASS**  
Floors  
Foot Spas  
Garbage Cans  
Highchairs  
Mirrors  
Showers  
Shower Stalls  
Sinks  
Stainless Steel  
Tables  
Toilets  
Toilet Bowls  
Tubs (Fiberglass)  
Tiles, glazed  
Urinals  
Vinyl  
Walls  
Windows  
Whirlpool baths

**and other hard nonporous inanimate surfaces made of:**

Glazed ceramic  
Glazed porcelain  
Metal  
Plastic  
Sealed Stone  
Stainless Steel

**DIRECTIONS FOR USE:**

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

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This product is not for use in residential settings.

**This product contains hydrogen peroxide. This product must not be mixed or stored with products containing ammonia, bleach, or other oxidizing agents. Contact with metals, metal ions, wood dust, or wood shavings may cause product decomposition.**

**CLEANING/ DEODORIZING DIRECTIONS:** For Cleaning and deodorizing, dilute 2 oz. of concentrate per gallon of water. Cleaning may be accomplished with a clean mop, sponge, squeegee, wet vacuum system or a trigger spraying device. Spray 6-8 inches from the surface to be treated, thoroughly wetting the surface. After cleaning, remove suspended soils with a clear water rinse, vacuum pick up, or by wiping with a clean mop, sponge, squeegee, or cloth or allow to air dry. Do not breathe spray.

**DISINFECTION/ CLEANING/ DEODORIZING DIRECTIONS:** To disinfect hard non-porous inanimate surfaces, dilute 6.5 oz. of concentrate per gallon of water (1:20). Remove heavy soil deposits from surfaces. Apply to surfaces using a cloth, mop, sponge, or coarse trigger sprayer. Spray 6-8 inches from surface to be treated, thoroughly wetting the surface. Allow to remain wet for 10 minutes. Rub with brush, sponge, or cloth. Do not breathe spray. Wipe area with a clean cloth or allow to air dry. This product is not to be used as a terminal sterilant/ high-level disinfectant on any surface or instrument that (1) is introduced into the human body either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise normally sterile areas of the body.

**CLEANING AND DISINFECTING OF WHIRLPOOLS AND FOOTBATHS:**

To remove body oils, dead tissue, soil and all other buildups or organic matter on inanimate surfaces after using the footbath, drain the water and thoroughly clean all hard, nonporous surfaces with soap or detergent, then rinse with water. Wet surfaces with a use solution of 6.5 oz. per gallon of water (1:20). Apply solution to exposed surfaces with a cloth, mop, sponge or sprayer. For spray applications, use a coarse spray device. Do not breathe spray. Brush or swab thoroughly and allow solution to stand for 10 minutes. After the bath has been thoroughly disinfected, rinse all surfaces with clean fresh water. Whirlpools and footbaths should not be used until treatment has set and dried.

**TOILET BOWLS/ URINALS:**

Swab bowl with brush to remove heavy soil prior to cleaning or disinfecting. Clean by applying use-solution around the bowl and up under the rim. Stubborn stains may require brushing. To disinfect, first remove or expel over the inner trap the residual bowl water. Pour in 2 oz. of the use-solution. Swab the bowl completely using a scrub brush or mop, making sure to get under rim. Let stand for 10 minutes. Rinse by flushing.

**\*Virucidal Activity:** When used as directed at 5 oz per gallon of water (1:20), 200 ppm hard water in the presence of 5% organic soild load, this product (Kills) is effective against Influenza Type A (ATCC VR-100), Respiratory Syncytial Virus, Rotavirus (Strain WA) Herpes Simplex Virus Type 2 (ATCC VR-734) with a 10 minute contact time.

**\*This product kills HIV-1 in 1 (one) minute and Hepatitis B Virus (HBV) in 10 minutes on pre-cleaned environmental surfaces/ objects previously soiled with blood/body fluids in settings in which there is an expected likelihood of soiling of inanimate surfaces/ objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS)**



# **SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 and HBV ON SURFACES/ OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** Disposable protective gloves, gowns, face masks, or eye coverings as appropriate must be worn during all cleaning of body fluids, blood, and decontamination procedures.

**Cleaning Procedures:** Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

**Contact Time:** Allow surface to remain wet for 1 minute to kill HIV-1 and 10 minutes for all other bacteria and viruses claimed.

**Disposal of Infectious Material:** Blood and other body fluids should be autoclaved and disposed of in accordance with Federal, State, and local regulations for infectious waste disposal.

**GLASS CLEANING:** Dilute 1 oz. of product per gallon of water. Spray onto glass surface. Use through a coarse hand pump trigger sprayer device. Do not breathe spray. Wipe dry with an absorbent cloth or towel.

## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER:** Corrosive. Causes irreversible eye damage. Causes skin burns. Harmful if swallowed or inhaled. Do not get in eyes, on skin or on clothing. Wear eye protection (goggles, safety glasses with side shields, or face shield). Wear coveralls worn over long-sleeved shirt and long pants, chemical resistant gloves, socks, and chemical resistant footwear. Avoid contamination of food. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing, and wash clothing before reuse.

### **PHYSICAL OR CHEMICAL HAZARDS:**

This product is an oxidizer. Do not store near heat, flame, or in direct sunlight. Avoid storage at elevated temperatures. Do not store near wood shavings, dust or similar combustible materials.

## **STORAGE AND DISPOSAL**

**<For Containers 1 gallon or less, use the following statement>**

Keep product under locked storage, inaccessible to children. Do not reuse empty container. Wrap empty container and discard in trash or recycle.

**<For Containers Larger than 1 Gallon, use the following statements >**

### **STORAGE AND DISPOSAL**

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

**Pesticide Storage:** Do not reuse empty container.

**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:**

**(Plastic Containers)**

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, stay out of smoke.

**<For containers 5 gallons or more, the following Environmental Hazard Statement Must be used in addition to the Storage and Disposal Statements indicated above>**

**ENVIRONMENTAL HAZARDS:**

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.

**<Optional Marketing Language/ Graphics for Use through Dispensing Systems>**

Use only with Betco's **FASTDRAW™** System.

|   |  |   |  |   |
|---|--|---|--|---|
|  | <p><b>TRIGGER SPRAYERS</b></p> <ol style="list-style-type: none"> <li>1. Fill bottle from short tube on dispenser.</li> <li>2. Apply to surface as specified above.</li> </ol> |  |  | <p><b>MOP BUCKETS OR AUTOSCRUBBERS</b></p> <ol style="list-style-type: none"> <li>1. Fill bucket or autoscrubber from long hose on dispenser.</li> <li>2. Set up "Wet Floor" signs.</li> <li>3. Apply to floor as specified above.</li> </ol> |
|---|--|---|--|---|



**<Optional Customer Information Graphics>**

|   |   |
|---|---|
| <p><b>MSDS</b><br/>Information<br/>1-800-891-4965</p> | <p><b>QUESTIONS?<br/>COMMENTS?</b><br/>1-800-777-9343</p> |
|---|---|



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