

211-40

2/16/2011

1/8

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Richard Kueser  
Central Solutions, Inc.  
401 Funston Road  
Kansas City, KS 66115

FEB 16 2011

SUBJECT: Q4.5-5.OPB-4.5  
EPA Registration Number: 211-40  
Application Dated: January 18, 2011  
Receipt Date: January 19, 2011

Dear Mr Kueser:

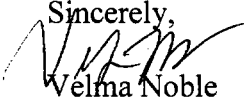
This letter acknowledges receipt of the notification identified above submitted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

- Revising Storage and disposal statements.

Based on a review of the submitted information, this notification is acceptable. Your proposed changes will be made part of the record for this file.

**General Comments**

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0109 or Velma Noble at (703) 308-6233.

Sincerely,  
  
Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

| CONCURRENCES |  |  |  |  |  |  |  |
|--------------|--|--|--|--|--|--|--|
| SYMBOL       |  |  |  |  |  |  |  |
| SURNAME      |  |  |  |  |  |  |  |
| DATE         |  |  |  |  |  |  |  |

Please read instructions on reverse before using form.

Registration Form

Form Approved

OMB No. 2070-0080

Print Form



United States Environmental Protection Agency Washington, DC 20460

|                                     |              |
|-------------------------------------|--------------|
| <input type="checkbox"/>            | Registration |
| <input checked="" type="checkbox"/> | Amendment    |
| <input type="checkbox"/>            | Other        |

OPP Identifier Number

Application for Pesticide - Section I

|  |   |  |
|--|---|--|
| 1. Company/Product Number<br>211-40  | 2. EPA Product Manager<br>Velma Noble   | 3. Proposed Classification<br><input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name)<br>Q4.5-5.OPB-4.5  | PM#<br>Team 31  |  |
| 5. Name and Address of Applicant (Include ZIP Code)<br>Central Solutions, Inc.<br>401 Funston Road<br>Kansas City, KS 66115<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. _____<br>Product Name _____ |  |

Section - II

|  |  |
|--|--|
| <input type="checkbox"/> Amendment - Explain below.  | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>Nov. 18, 2010</u> | <input type="checkbox"/> "Me Too" Application.   |
| <input type="checkbox"/> Notification - Explain below.   | <input type="checkbox"/> Other - Explain below.  |

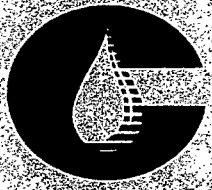
Explanation: Use additional page(s) if necessary. (For section I and Section II.)  
Revising Storage and Disposal statements as requested in letter dated Nov 18, 2010.

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 type="checkbox"/> Metal   | <input checked="" type="checkbox"/> Plastic |
|   |  |   |                       | <input type="checkbox"/> Glass   | <input type="checkbox"/> Paper              |
| * Certification must be submitted   | If "Yes" Unit Packaging wgt.   | No. per container   | If "Yes" Package wgt. | No. per container  | Other (Specify) _____                       |
| 3. Location of Net Contents Information<br><input checked="" type="checkbox"/> Label <input type="checkbox"/> Container   |  | 4. Size(s) Retail Container<br>4,16,32oz,1,5,55gal, 2L, 3L  |                       | 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><input type="checkbox"/> Lithograph<br><input type="checkbox"/> Paper glued<br><input type="checkbox"/> Stenciled |  |   |                       | <input checked="" type="checkbox"/> Other Silk-screened  |   |

Section - IV

|   |  |   |
|---|--|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)   |  |   |
| Name<br>Richard Kueser  | Title<br>Regulatory Compliance Dir         | Telephone No. (Include Area Code)<br>913-621-6542 |
| Certification<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. |  | 6. Date Application Received (Stamped)            |
| 2. Signature<br>  | 3. Title<br>Regulatory Compliance Director |   |
| 4. Typed Name<br>Richard Kueser   | 5. Date<br>10-18-2011<br><i>(10)</i>       |   |



# CENTRAL SOLUTIONS, INC.

913.621.6542  
1.800.255.0262  
Fax: 913.621.7031  
401 Funston Rd.  
Kansas City, Kansas 66115

Formulation • Development • Production  
www.centraisolutions.com

Subject: Notification Amendment  
EPA Registration Number 211-40  
Registered Name: Q4.5-5.0PB-4.5  
Amendment Dated 1/18/2011

Notification of efficacy claim against H1N1 Virus and Storage & Disposal label change per PR Notice 95-2.

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.

  
Richard Kueser  
Regulatory Compliance Director

2-11-2011  
Date

4/8

(Administrative Note: The following text is required for front panel labeling):

# Q4.5-5.0PB-4.5

**DISINFECTANT - DEODORIZER - FUNGICIDE - VIRUCIDE\*  
WHIRLPOOL CLEANER DESIGNED FOR HOSPITAL,  
NURSING HOME, AND INSTITUTIONAL USE**

**Active Ingredients:**

n-Alkyl (60%C<sub>14</sub> , 30%C<sub>16</sub> , 5%C<sub>12</sub> , 5%C<sub>18</sub>) dimethyl benzyl ammonium chlorides....2.25%  
n-Alkyl (68%C<sub>12</sub> , 32%C<sub>14</sub> ) dimethyl ethylbenzyl ammonium chlorides.....2.25%

**Inert Ingredients:**.....95.50%  
**Total:** 100.00%

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

**SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

## Central Solutions, Inc.

401 Funston Road  
Kansas City, KS 66115

EPA Reg. No. 211-40  
EPA Est. No. 211-KS-1

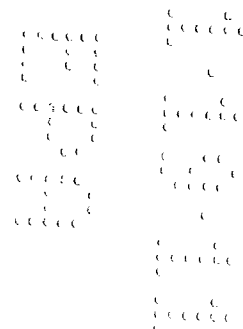
NET CONTENTS: X GALLONS

(Administrative Note: The following text is optional on front panel labeling):

Whirlpool Cleaner Designed for Hospital, Nursing Home, and Institutional Use  
Whirlpool Cleaner Designed for Health Care Institutions  
Formulated for Whirlpool Bathing Systems  
Formulated for Hospitals and Long-Term Care Facilities  
Whirlpool Cleaner

\*\*Non-Critical Medical Device Uses

(Side or Back Panels)



5/8

(Administrative Note: The following text is required for all labeling):

## PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

### DANGER

Keep out of reach of children. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear goggles/face shield, rubber gloves, and protective clothing. Harmful if absorbed through skin. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

| <b>FIRST AID</b>   |  |
|--|--|
| <b>If in eyes</b>  | <ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with plenty of water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>                                    |
| <b>If on skin or clothing</b>  | <ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>   |
| <b>If inhaled</b>  | <ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>  |
| <b>If swallowed</b>  | <ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give <b>any</b> liquid to this person.</li> <li>• Do not give anything by mouth to an unconscious person</li> </ul> |
| <b>HOTLINE NUMBER</b>  |  |
| <b>For emergency medical advice, call your local poison control center or a doctor. Have the product container or label with you when seeking medical advice or treatment.</b> |  |
| <b>NOTE TO PHYSICIAN</b>   |  |
| Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.                |  |

(Administrative Note: The First Aid Statement's grid format will be used if market label space permits; otherwise a paragraph format will be used)

*(Administrative Note: The "Environmental Hazards" statement is for container sizes of 5 gallons or greater):*

### **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. This product is toxic to fish and aquatic organisms.

### **STORAGE AND DISPOSAL**

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

**PESTICIDE STORAGE** - Store in a securely closed original container. Store in area that will prevent cross contamination of other pesticides, fertilizer, food, and feed. Avoid storage at temperature extremes or in sunlight.

**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** - Nonrefillable container. Do not reuse or refill this container. If empty, place in trash or offer for recycling.

#### **Less than or equal to 5 gallons:**

Clean container promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

#### **Greater than 5 gallons:**

Clean container promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

(Administrative Note: The following text is optional for all labeling):

### PRODUCT COMPOSITION

*Q4.5-5.OPB-4.5* is a disinfectant, deodorizer, fungicide, and virucide\* cleaner designed for hospital, nursing home, and institutional use. *Q4.5-5.OPB-4.5* contains two active twin chain quaternary ammonium compounds (listed as active ingredients) for bactericidal efficacy. Inert ingredients include a balance of alkaline builders, non-ionic surfactants, and odor counteractants to enhance the cleaning and odor control characteristics. This formulation is designed to clean and disinfect bathing and therapy equipment. When used as directed, *Q4.5-5.OPB-4.5* has been found effective for use on all fiberglass, stainless steel, and chrome plated surfaces of bath, therapy, whirlpools, and patient transfer equipment.

#### \*\*Non-Critical Medical Device Uses

*Q5.5-5.5NPB-2.5HW* is a general purpose disinfectant that may be used to clean and disinfect hard, non-porous, inanimate, non-critical medical and dental equipment surfaces. *Q5.5-5.5NPB-2.5HW* may also be used to clean and/or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

*Q4.5-5.OPB-4.5* is appropriate for use on non-critical medical devices\*\*

**FOR CLEANING (Administrative Note: Manufacture's Brand Tub Name Inserted Here) FIBERGLASS BATH AND THERAPY EQUIPMENT:** To remove body oils, dead tissue, hard water, and all other buildups or organic matter on inanimate surfaces after using the whirlpool unit, drain the water and refill with fresh water to just cover the intake valve. Add two ounces of *Q4.5-5.OPB-4.5* for each gallon of water in the unit at this point. Briefly start the pump to circulate the solutions. Turn off pump. Wash down the unit sides, seat of the chairlift, and any/all related equipment with a clean swab or sponge. After the unit has been thoroughly cleaned, drain solutions from the unit and rinse any/all cleaned surfaces with fresh water. The unit is ready for re-use. Product to surface contact time must be at least 10 minutes for proper disinfection.

(Administrative Note: The following text is required for all labeling. If a sub-registrant desires to delete claims against select, specific organisms, it must do so with the approval of the basic registrant.)

### DIRECTIONS FOR USE

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

**DISINFECTION:** To disinfect hard, non-porous, inanimate surfaces (such as fiberglass and stainless steel tubs and chair surfaces, chrome plated intakes and lifts, etc.), apply properly diluted *Q4.5-5.OPB-4.5* with mop, cloth sponge, mechanical sprayer, or hand pump trigger sprayer so as to wet all surfaces thoroughly. For routine disinfection, proper dilution is 2 ounces of *Q4.5-5.OPB-4.5* per gallon of water (1:64). Allow to remain wet for 10 minutes and then let air dry. For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh dilution for each use.

**SANITIZATION:** To sanitize non-porous, non-food contact surfaces, add 2 ounces of *Q4.5-5.OPB-4.5* per gallon of water (1:64). Treated surfaces must remain wet for 30 seconds.

### PERFORMANCE DATA

Efficacy tests have demonstrated that *Q4.5-5.OPB-4.5* is an effective bactericide, fungicide, and virucide\* on hard, non-porous, inanimate surfaces in the presence of moderate amounts of organic soil (5% blood serum). Germicidal, fungicidal, and virucidal\* testing has been performed using A.O.A.C. protocol testing as required by the EPA at a use-dilution of 1:64 (two ounces per gallon of water) in the presence of 5% blood serum (used to simulate organic soil load), at 20 degrees celcius with an exposure time of 10 minutes.

**BACTERICIDAL:** The broad spectrum activity of *Q4.5-5.OPB-4.5* has been confirmed against the following organisms: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella pneumoniae*, *Serratia marscenscens*, *Salmonella enterica*, *Methicillin resistant Staphylococcus aureus (MRSA)*, *Proteus vulgaris*.

**FUNGICIDAL:** *Q4.5-5.OPB-4.5*'s efficacy as a fungicide has been confirmed through testing against the following pathogenic fungi: *Trichophyton mentagrophytes*, *Candida albicans*

**\*VIRUCIDAL:** Testing of *Q4.5-5.OPB-4.5* has confirmed its virucidal activity against the following viruses: *Influenza A2-Asian* (representative of the common flu virus), *Herpes simplex Type 1* (causative agent of fever blisters), *Adeno virus type 2* (causative agent of upper respiratory infections), *Vaccinia virus* (representative of the pox virus group), *HIV-1* (AIDS Virus)

(Optional copy for claim against H1N1 Virus – Swine Flu)

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. **Q4.5-5.OPB-4.5** 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 H1N1 (formerly called swine flu).

or

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.

or

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

or

Kills Pandemic 2009 H1N1 influenza A virus (formerly known as swine flu)

or

Kills Pandemic 2009 H1N1 influenza A virus.

**\*KILLS HIV-1 ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of inanimate surfaces/objects likely to be soiled 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). Contact time: ten (10) minutes.

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST AIDS (HIV-1 VIRUS) ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS WITH TEN (10) MINUTE CONTACT TIME.**

**PERSONAL PROTECTION:** Disposable gloves must be worn when cleaning blood, body fluids, or contaminated items. Hands must be washed immediately and thoroughly after gloves are removed, or if hands are contaminated with blood or body fluids. Masks and protective eyewear or faceshields must be worn during cleaning procedures involving blood or body fluids. Gowns or aprons must be worn during cleaning procedures for protection against splashes of blood or other body fluids.

**CLEANING PROCEDURE:** Blood and other fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant. After cleaning is complete, follow disinfection described previously.

**DISPOSAL OF INFECTIOUS MATERIALS:** Contaminated waste and blood and other body fluids must be autoclaved and disposed according to local regulations for infectious waste disposal.

**SANITIZATION:** At a use-dilution of 1:64 (2 ounces per gallon of water), in 400 ppm hardwater, **Q4.5-5.OPB-4.5** is an effective sanitizer on non-porous, non-food contact surfaces against the following organisms: *Staphylococcus aureus*, *Enterobacter aerogenes*

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly 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 enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.