

211-40

1098

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

NOV 18 2010

SUBJECT: Q4.5-5.OPB-4.5
EPA Registration Number: 211-40
Application Dated: October 18, 2010
Receipt Date: October 19, 2010

Dear Mr Kueser:

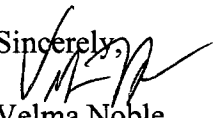
This letter acknowledges receipt of the notification identified above submitted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

1. Adding Virucidal Performance claims for H1N1 virus.
2. Updating nomenclature from Salmonella Choleraesuis to Salmonella Enterica.

Based on a review of the submitted information, this notification is acceptable. Your proposed direction for use 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 | | | | | | | |

2018

Print Form

Please read instructions on reverse before completing form.

Form Approved. MB No. 2070-0060



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

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>FEB 3, 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 label to change the Storage and Disposal copy as required by PR Notice 2007-4; to add labeling claim against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/2010; and Label Revision - Updating nomenclature used for claimed organism, Salmonella Choleraesuis to currently recognized listing, Salmonella Enterica.

Section - III

| | | | | | |
|--|--|---|---|---|----------------------------------|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | | <input checked="" type="checkbox"/> Metal | <input type="checkbox"/> Plastic |
| * Certification must be submitted | If "Yes" Unit Packaging wgt. NA | No. per container NA | If "Yes" Package wgt | <input type="checkbox"/> Glass | <input type="checkbox"/> Paper |
| | | | No. per container | <input type="checkbox"/> Other (Specify) _____ | |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container 4,16,32oz, 1,5,5 gal, 2L, 3L | | 5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <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 Richard Kueser | | Title Regulatory Compliance Dir | | Telephone No. (Include Area Code) 913-621-6542 | |
| 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 both under applicable law. | | | | | 6. Date Application Received (Stamped) |
| 2. Signature | | 3. Title Regulatory Compliance Dir | | | |
| 4. Typed Name Richard Kueser | | 5. Date 10-18-2010 | | | |
| | | | | | |

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(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%C₁₄, 30%C₁₆, 5%C₁₂, 5%C₁₈) dimethyl benzyl ammonium chlorides....2.25%
n-Alkyl (68%C₁₂, 32%C₁₄) 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

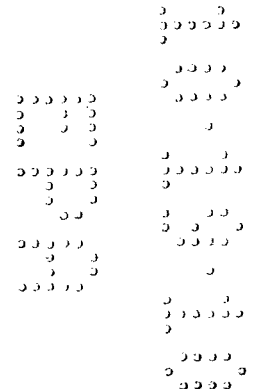
NET CONTENTS: X GALLONS

(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)



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(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.

Offer for recycling, if available.

or

Offer for reconditioning, if appropriate

Less than or equal to 5 gallons:

Clean container promptly after emptying.

or

Triple rinse container (or equivalent) 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 1/4 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.

or

Triple rinse container (or equivalent) promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 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.

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

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. **Q4.5-5.0PB-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 leaning 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, **Q4.5-5.0PB-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.

Handwritten marks and symbols, possibly a signature or initials, located in the bottom right corner of the page.