

1839-102

01-07-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Thomas W. Isaac  
Sr. Regulatory Specialist  
Stepan Company  
22 W. Frontage Rd.  
Northfield, IL 60093

JAN -7 2010

Subject: NP 4.5 (D&F) Detergent/Disinfectant  
EPA Reg. No. 1839-102  
Application Dated: December 10, 2009  
Receipt Date: December 11, 2009

Dear Thomas W. Isaac

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 Amendment**

Adding marketing language for the Pandemic H1N1

**Comments**

Based on a review of the material submitted, the following comments apply:  
This application for notification to add marketing language for the Pandemic H1N1 and minor label language 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 (7510P)

**CONCURRENCES**

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

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

Print Form



United States  
Environmental Protection Agency  
Washington, DC 20460

 Registration  
 Amendment  
 Other

OPP Identifier Number

### Application for Pesticide - Section I

|                                                                                                                                                                                |                                       |                                                                                                                                                                                                                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Company/Product Number<br>1839-102                                                                                                                                          | 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>NP 4.5 (D&F) Detergent/Disinfectant                                                                                                               | PM#<br>31                             |                                                                                                                                                                                                                         |
| 5. Name and Address of Applicant (Include ZIP Code)<br>Stepan Company<br>22 W. Frontage Rd.<br>Northfield, IL 60093<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><input checked="" type="checkbox"/> 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 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.)

Addition of Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus per EPA Guidance Document dated 10/21/09.

### Section - III

1. Material This Product Will Be Packaged In:

|                                                                                                                                                                                                                          |                                                                                          |                                                                                                   |                                                                                                                                                                                                                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Child-Resistant Packaging<br><input checked="" type="checkbox"/> Yes*<br><input type="checkbox"/> No                                                                                                                     | Unit Packaging<br><input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | Water Soluble Packaging<br><input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | 2. Type of Container<br><input checked="" type="checkbox"/> Metal<br><input checked="" 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.<br>1 oz.      No. per container<br>multiple                 | 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>qt., 1.55 gals                                                     | 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 checked="" type="checkbox"/> Lithograph <input checked="" 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<br>Thomas W. Isaac                                                                                                                                                                                                                                                            | Title<br>Sr. Regulatory Specialist    | Telephone No. (Include Area Code)<br>(847)501-2309                                                                                                                                                         |
| <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. |                                       | 6. Date Application Received<br><br><b>(Stamped)</b><br>C O C C C C<br>C O C C C C<br>C O C C C C<br>C O C C C C<br>C O C C C C<br>C O C C C C<br>C O C C C C<br>C O C C C C<br>C O C C C C<br>C O C C C C |
| 2. Signature<br><i>Thomas W. Isaac</i>                                                                                                                                                                                                                                             | 3. Title<br>Sr. Regulatory Specialist |                                                                                                                                                                                                            |
| 4. Typed Name<br>Thomas W. Isaac                                                                                                                                                                                                                                                   | 5. Date<br>December 10, 2009          |                                                                                                                                                                                                            |

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December 10, 2009

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

ATTN: Ms. Velma Noble  
PM-31  
Regulatory Management Branch I

RE: CD 4.5 (D&F) Detergent/Disinfectant  
EPA Reg. No. 1839-102

Dear Ms. Noble:

This Notification proposes the following label addition/revision:

- Addition of Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/09.

**LABELS:**

Five (5) draft labels are enclosed. One label is highlighted for Agency review.

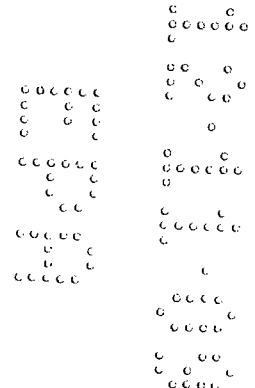
Should the Agency need additional information in order to process this notification, please feel free to contact me immediately at (847) 501-2309 or via email: [tisaac@stepan.com](mailto:tisaac@stepan.com).

Sincerely,  
STEPAN COMPANY

Thomas W. Isaac  
Sr. Regulatory Specialist

Enclosures: Notification administrative package, labels (5 copies)  
TWI:slf

119-09-TI-EPA-1839-102



5/8

# CD 4.5 (D&F) Detergent/Disinfectant

CLEANER  
DETERGENT  
FUNGICIDE (against pathogenic fungi)  
MILDEWSTAT (on hard inanimate surfaces)  
Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu)

DISINFECTANT  
DEODORIZER  
\*VIRUCIDE

**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%         |
| <b>INERT INGREDIENTS</b> .....                                                                 | <u>95.50%</u> |
| TOTAL .....                                                                                    | 100.00%       |

**KEEP OUT OF REACH OF CHILDREN**

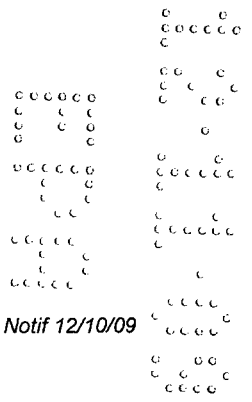
## DANGER

See side panels for additional precautionary statements.

EPA REG. NO. 1839-102  
EPA EST. NO. 1839-IL-01

**STEPAN COMPANY**  
22 West Frontage Road  
Northfield, IL 60093

NET CONTENTS



### DIRECTIONS FOR USE

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

CD 4.5 (D&F) Detergent/Disinfectant has been designed to provide effective cleaning, deodorizing and disinfection specifically for hospitals, nursing homes, schools, food processing plants and food service establishments where housekeeping is of prime importance in controlling the hazard of cross contamination.

This product, when used as directed, is formulated to disinfect inanimate hard surfaces: walls, floors, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, sink tops, toilet bowls, cabinets, tables, chairs, telephones, and bed frames. For larger areas such as operating rooms, patient care facilities, and restrooms, this product is designed to provide both general cleaning and disinfecting.

In addition, this product deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls and other areas which are prone to odors caused by microorganisms.

*(For labels that list medical premises and/or stainless steel surfaces, one of the following statements must be used:)*

This product is not 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 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.

or

This product is not for use on medical device surfaces.

**DISINFECTION** - To disinfect hard inanimate surfaces, add 2 ounces of this product per gallon of water. Apply solution with a mop, cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, remove excess liquid.

**To disinfect toilet bowls:** flush toilet, add 2 ounces of this product directly to the bowl water. Swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

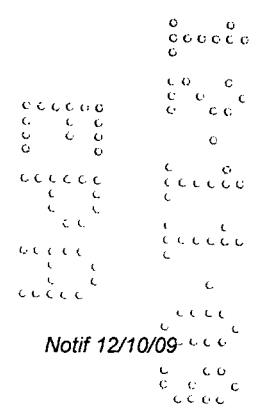
**To disinfect food processing premises:** floors, walls, and storage areas, add 2 ounces of this product per gallon of water. For heavily soiled areas, a pre-cleaning step is required. Apply solution with a mop, cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid. Before using this product, food products and packaging materials must be removed from the area or carefully protected. After use, all surfaces in the area must be thoroughly rinsed with potable water.

**To disinfect food service establishment food contact surfaces:** countertops, appliances, tables, add 2 ounces of this product per gallon of water. Before using this product, food products and packaging materials must be removed from area or carefully protected. For heavily soiled areas, a pre-cleaning step is required. Apply solution with a cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow the surface to remain wet for 10 minutes, then remove excess liquid and rinse the surface with potable water. This product cannot be used to clean the following food contact surfaces: utensils, glassware and dishes.

**BACTERICIDAL ACTIVITY** - When diluted at 2 ounces per gallon of water, this product exhibits effective disinfectant activity against the organisms: Pseudomonas aeruginosa, Salmonella choleraesuis, Staphylococcus aureus and meets all requirements for hospital use.

**FUNGICIDAL ACTIVITY** - At the 2 ounces per gallon dilution, this product is also fungicidal against the pathogenic fungi, Trichophyton mentagrophytes (Athlete's Foot Fungus), when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, exercise facilities or other clean, hard, non-porous, surfaces commonly contacted by bare feet.

**\*VIRUCIDAL ACTIVITY** - This product when used on environmental inanimate hard surfaces at 2 ounces per gallon of water exhibits effective virucidal activity against Influenza A<sub>2</sub>/Asian (representative of the common flu virus), Herpes simplex type 1 (causative agent of fever blisters), Adenovirus type 2 (causative agent of upper respiratory infections), and Vaccinia virus (representative of the pox virus group).



(optional statements to appear anywhere on the 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 (Product Name) 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 (Product Name) 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).
- Kills Pandemic 2009 H1N1 Influenza A virus.

**MILDEWSTAT** - To control mold and mildew and the odors they cause on pre-cleaned, hard, non-porous surfaces add 2 ounces of this product per gallon of water. Apply solution with a cloth, mop or sponge making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth appears.

**DEODORIZATION** - To deodorize, apply this product as indicated under the heading **DISINFECTION**.

**EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE, FUNGICIDE AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).**

**PRECAUTIONARY STATEMENTS**  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

**DANGER**

KEEP OUT OF REACH OF CHILDREN. CORROSIVE. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, rubber gloves, and protective clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**FIRST AID**

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

**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. Call a poison control center or doctor for treatment advice.

**If on skin or clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

**If swallowed:** Call 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 further treatment advice.

**(OPTIONAL)** You may contact xxx/xxx-xxxx for emergency medical treatment information.

**NOTE TO PHYSICIAN**

Probable mucosal damage may contraindicate the use of gastric lavage.

(Note: If container size is 5 gallons or greater, the following Environmental Hazards statement must 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.

