

1839-97

2/18/2010  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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FEB 18 2010

Mr. Thomas W. Isaac  
Senior Regulatory specialist  
Stephen Company  
22 W. Frontage Rd.  
Northfield, Illinois 60093

Subject: **NP 12.5 (D&F) Detergent/Disinfectant**  
EPA Registration Number 1839-97  
Application Dated November 20, 2009  
EPA Received Date November 23, 2009

Dear Mr. Isaac:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

**Proposed Amendment:**

- Revised Container Disposal Statements
- Add labeling claims against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/09

**General Comments:**

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,

  
Velma Noble

Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Enclosure: stamped label

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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# NP 12.5 (D&F) Detergent/Disinfectant

CLEANER  
DETERGENT  
DEODORIZER

DISINFECTANT  
\* VIRUCIDE

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

## 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 chloride .....	6.25%
n-Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> ) dimethyl	
ethylbenzyl ammonium chloride .....	6.25%
INERT INGREDIENTS .....	87.50%
Total	100.00%

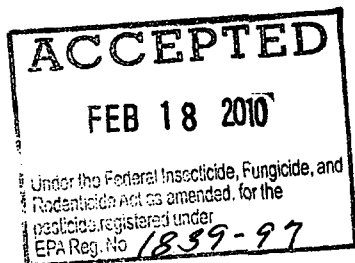
KEEP OUT OF REACH OF CHILDREN

## DANGER

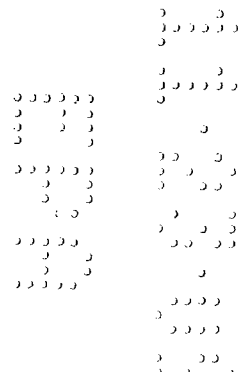
See side panels for additional precautionary statements.

EPA REG. NO. 1839-97  
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.

NP 12.5 (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 environmental 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 0.5 ounce 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 and then let air dry. For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

**To disinfect toilet bowls**, flush toilet, add 0.5 ounce 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.

**To disinfect food processing premises:** floors, walls, and storage areas, add 0.5 ounce 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 0.5 ounce of this product per gallon of water. 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. Before using this product, food products and packaging materials must be removed from area or carefully protected.

**BACTERICIDAL ACTIVITY** - When diluted at 0.5 ounce per gallon of water, this product exhibits effective disinfectant activity against the organisms: *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schottmuelleri*, *Streptococcus salivarius*, *Brevibacterium ammoniagenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, and *Enterobacter aerogenes* and meets all requirements for hospital use.

**FUNGICIDAL ACTIVITY** - At the 0.5 ounce 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.

**MILDEWSTAT** - To control mold and mildew and the odors they cause on pre-cleaned, hard, non-porous surfaces add 0.5 ounce 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.

**\* VIRUCIDAL ACTIVITY** - This product, when used on environmental inanimate hard surfaces at 0.5 ounce per gallon of water, exhibits effective virucidal activity against Influenza A2/Asian (representative of the common flu virus), Herpes simplex (causative agent of fever blisters), Adenovirus type 5 (causative agent of upper respiratory infections), Vaccinia virus (representative of the Pox virus group) and Human Immunodeficiency Virus (HIV-1).

*(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.

**KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings (Hospitals, Nursing Homes) or other 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 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, or eye coverings.

**CLEANING PROCEDURES:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

**CONTACT TIME:** Allow surface to remain wet for 10 minutes.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

**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 or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, rubber gloves, and protective clothing. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.

**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.

## STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

**PESTICIDE STORAGE** - Store in a dry place no lower in temperature than 50°F or higher than 120°F.

**CONTAINER DISPOSAL** – Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container promptly after emptying.

*(Containers 5 gallons or less)*

Triple rinse as follows: Fill container ¼ full with water and recap. Agitate vigorously. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

*(Containers greater than 5 gallons):*

Triple rinse as follows: Fill container ¼ full with water. 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. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into the application equipment or mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

**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.