

1839-80

2/18/2010
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1045

FEB 18 2010

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

Subject: **NP 12.5 Detergent/Disinfectant**
EPA Registration Number 1839-80
Application Dated November 19, 2009
EPA Received Date November 20, 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. per PR Notice 2007-4
- Change the Sanitizing Solution reference to 40CFR180.940 from 21 CFR178.1010
- 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)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

NP 12.5 Detergent/Disinfectant

CLEANER
DETERGENT
SANITIZER

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 ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chlorides	6.25%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl	
ethylbenzyl ammonium chlorides	6.25%
INERT INGREDIENTS	<u>87.50%</u>
Total	100.00%

EPA REG. NO. 1839-80
EPA EST. NO. 1839-IL-01

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panels for additional precautionary statements.

STEPAN COMPANY

22 West Frontage Road • Northfield, IL 60093

NET CONTENTS

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:

FEB 18 2009
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

1839-80

3045

DIRECTIONS FOR USE

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

NP 12.5 Detergent/Disinfectant is designed to provide effective cleaning, deodorization, sanitization and disinfection specifically for hospitals, nursing homes, schools, food processing plants, 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 hard, non-porous, inanimate, environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, toilet bowls, sink tops, cabinets, tables, chairs and telephones. For larger areas: operating rooms, patient care facilities and restrooms, this product is designed to provide both general cleaning and disinfecting.

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.

This product sanitizes previously cleaned and rinsed non-porous food contact surfaces: tanks, chopping blocks, counter tops, drinking glasses, and eating utensils.

(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 inanimate, hard 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, then remove excess liquid. Remove gross filth or heavy soil prior to application of this product. 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.

BACTERICIDAL ACTIVITY - When diluted at the rate of 0.5 ounce per gallon of water, this product exhibits effective disinfectant activity against the organisms: *Pseudomonas aeruginosa* PRD 10, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schottmuelleri*, *Salmonella choleraesuis*, *Streptococcus salivarius*, *Brevibacterium ammoniagenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, *Enterobacter aerogenes*, and *Staphylococcus aureus* and meets all requirements for hospital disinfectants.

MILDEWSTAT - To control mold and mildew 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.

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.

***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/Japan (representative of the common flu virus), Herpes Simplex Type 1 (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.

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Notif 11/19/09

(Alternative language for clean in place, closed loop dilution centers.)

WISCONSIN STATE DIVISION OF HEALTH - DIRECTIONS FOR EATING ESTABLISHMENTS

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with potable water.
4. Sanitize in a solution from the Closed Loop Dilution Center (200 ppm active quaternary). Immerse all utensils at least two minutes or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board to air dry.
6. Fresh sanitizing solution should be prepared at least daily or when visibly soiled or diluted.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196.13 of the Wisconsin Administrative Code.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER. KEEP OUT OF REACH OF CHILDREN. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if absorbed through skin. Harmful if swallowed. 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.