

1839-146

12/30/2009

17

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

DEC 30 2009

Subject: NP 1.8(D&F) Detergent/Disinfectant
EPA Reg. No. 1839-146
Application Dated: December 03, 2009
Receipt Date: December 04, 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 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								

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1839-146	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) NP 1.8 (D&F) Detergent/Disinfectant	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Stepan Company 22 W. Frontage Rd. Northfield, IL 60093 <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. _____ 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's Guidance document dated 10/21/09.

Section - III

1. Material This Product Will Be Packaged In: <div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> Child-Resistant Packaging <div style="border: 1px solid black; padding: 2px; display: inline-block;"> <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No </div> </div> <div style="width: 30%;"> Unit Packaging <div style="border: 1px solid black; padding: 2px; display: inline-block;"> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No </div> </div> <div style="width: 30%;"> Water Soluble Packaging <div style="border: 1px solid black; padding: 2px; display: inline-block;"> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No </div> </div> </div>				2. Type of Container <div style="border: 1px solid black; padding: 2px; display: inline-block;"> <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____ </div>	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container _____		If "Yes" Package wgt No. per container _____	
3. Location of Net Contents Information <div style="display: flex; justify-content: space-around;"> <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container </div>		4. Size(s) Retail Container qt, 1,5,55 gal		5. Location of Label Directions <div style="border: 1px solid black; padding: 2px; display: inline-block;"> <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product </div>	
6. Manner in Which Label is Affixed to Product		<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-right: 10px;"> <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled </div> <div style="margin-left: 20px;"> <input type="checkbox"/> Other _____ </div> </div>			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name <i>Thomas W. Isaac</i>	Title Sr. Regulatory Specialist	Telephone No. ⁹ (Include Area Code) (847) 501-2309
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 <i>Thomas W. Isaac</i>	3. Title Sr. Regulatory Specialist	
4. Typed Name Thomas W. Isaac	5. Date December 3, 2009	

December 3, 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: NP 1.8 (D&F) Detergent/Disinfectant
EPA Reg. No. 1839-146

Dear Ms. Noble:

This Notification proposes the following label addition/revision:

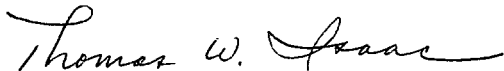
- Addition of Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/09.

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.

Sincerely,
STEPAN COMPANY



Thomas W. Isaac
Sr. Regulatory Specialist

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

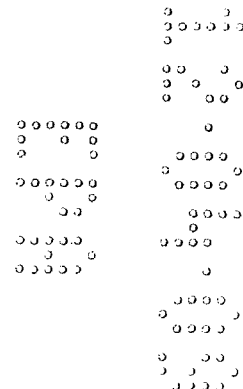
112-09-TI-EPA-1839-146



"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."

Thomas W. Isaac
Sr. Regulatory Specialist

Date: December 3, 2009



NP 1.8 (D&F) Detergent/Disinfectant

CLEANER	DISINFECTANT
DETERGENT	*VIRUCIDE
FUNGICIDE (against pathogenic fungi)	DEODORIZER
SANITIZER (non-food contact surfaces)	
MILDEWSTAT (on hard, inanimate surfaces)	
Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu)	

ACTIVE INGREDIENTS	
Octyl decyl dimethyl ammonium chloride	0.54%
Dioctyl dimethyl ammonium chloride	0.27%
Didecyl dimethyl ammonium chloride	0.27%
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chlorides	0.72%
INERT INGREDIENTS	<u>98.20%</u>
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

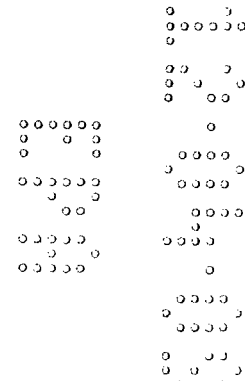
DANGER

See side panel for additional precautionary statements.

EPA REG. No. 1839-146
EPA EST. No. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road • Northfield, IL 60093

NET CONTENTS



6/7

DIRECTIONS FOR USE

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

NP 1.8 (D&F) Detergent/Disinfectant is a phosphate-free formulation designed to provide effective cleaning, deodorizing, non-food contact sanitizing, and disinfection specifically for schools, non-medical institutions and food processing plants 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, sink tops, toilet bowls, tables, chairs, telephones, bed frames, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, and cabinets.

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.

DISINFECTION - To disinfect inanimate, hard surfaces, add 2 ounces of this product per gallon of water. Apply solution with a mop, cloth, sponge, hand pump trigger sprayer or low pressure coarse mechanical sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes then remove excess liquid. For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

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.

To disinfect food-processing premises: floors, walls and storage areas, add 2 ounces 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. For sprayer application use a coarse spray. Allow to remain wet for 10 minutes, then remove excess liquid. Before using this product, food products and packaging materials must be removed from area or carefully protected. After use, all surfaces must be thoroughly rinsed with potable water.

BACTERICIDAL ACTIVITY - When diluted at the rate of 2 ounces per gallon of water, this product exhibits effective disinfectant activity against the organisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schottmuelleri*, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Streptococcus pyogenes*, *Shigella dysenteriae*, *Brevibacterium ammoniagenes*, *Salmonella typhi*, and *Serratia marcescens*.

*** 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/Brazil (lower respiratory tract disease), Herpes Simplex Type 1 (causative agent of fever blisters), 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 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.

FUNGICIDAL ACTIVITY - At the 2 ounces per gallon dilution this product is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* (Athlete's Foot Fungus), when used on hard surfaces in such areas as locker rooms, dressing rooms, shower and bath areas, and in exercise facilities.

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

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SANITIZATION OF NON-FOOD CONTACT SURFACES - To sanitize non-porous environmental surfaces: floors, walls, tables, add 5 ounces of this product per 4.5 gallons 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 30 seconds, then remove excess liquid. For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use. This product is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae*.

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 when handling. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash 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 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 a poison control center or doctor for treatment advice.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a 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 mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

(OPTIONAL): You may contact XXX/XXX-XXX 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 - Do not reuse empty container. Triple rinse empty container with water. Return metal drum then offer for reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers may be disposed of in a sanitary landfill, incinerated, or if allowed by local authorities, by burning. If burned, stay out of smoke.

For containers 1 gallon or less: Do not reuse empty container (bottle, can, bucket). Wrap container and put in trash.

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.