

1839-154

12/30/2009

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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

DEC 30 2009

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

Subject: Scented 10% BTC 2125M Disinfectant
EPA Reg. No. 1839-154
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 Antimicrobia
Division (7510P)

CONCURRENCES

SYMBOL	SURNAME	DATE					

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: Scented BTC® 2125M Disinfectant
EPA Reg. No. 1839-154

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.

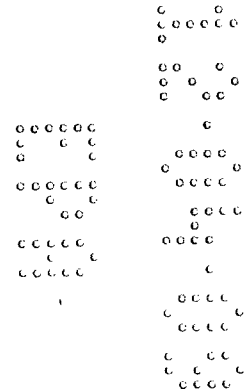
Should the Agency need additional information in order to process this notification, please feel free to contact me immediately at (847) 501-2309 or via email: tisaac@stepan.com.

Sincerely,
STEPAN COMPANY

Thomas W. Isaac
Sr. Regulatory Specialist

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

113-09-TI-EPA-1839-154



SCENTED 10% BTC[®] 2125M DISINFECTANT

DISINFECTANT * VIRUCIDE
DEODORIZER
Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu)

ACTIVE INGREDIENTS	
n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chlorides.....	5.0%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl	
ethylbenzyl ammonium chlorides.....	5.0%
INERT INGREDIENTS	<u>90.0%</u>
Total	100.0%

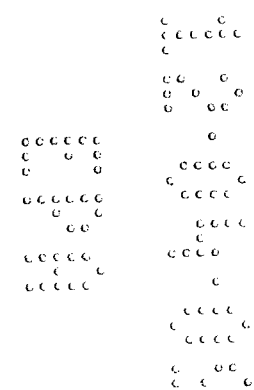
KEEP OUT OF REACH OF CHILDREN
DANGER

See side panel for additional precautionary statements.

EPA REG. NO. 1839-154
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.

Scented 10% BTC® 2125M Disinfectant is designed specifically for hospitals, animal quarters, kennels and institutions where disinfection and deodorization are of prime importance.

When used as directed, this product is formulated to disinfectant pre-cleaned inanimate, hard, non-porous surfaces: metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, toilets, cabinets, tables, chairs, walls, floors and bed frames.

This product deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, pet areas and any other areas which are prone to odors caused by microorganisms.

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

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.

OR

This product is not for use on medical device surfaces.

DISINFECTION - To disinfect pre-cleaned, inanimate, hard surfaces apply this product with mop, cloth, sponge, low pressure coarse sprayer or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid. For disinfection, a pre-cleaning step is required. Prepare a fresh solution for each use.

DILUTION RATES:

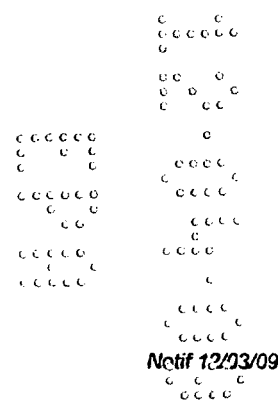
GENERAL DISINFECTION - Add 3 ounces of this product per 5 gallons of water for disinfection against Staphylococcus aureus, Salmonella choleraesuis, Listeria monocytogenes, and Yersinia enterocolitica.

HOSPITAL DISINFECTION - Add 3.5 ounces of this product per 5 gallons of water for disinfection against Pseudomonas aeruginosa.

DISINFECTION OF POULTRY EQUIPMENT, ANIMAL QUARTERS AND KENNELS - For disinfection of pre-cleaned poultry equipment (brooders, watering founts, feeding equipment), animal quarters and kennels, apply a solution of 3.5 ounces of this product per 5 gallons of water. Small utensils should be immersed in this solution. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Prior to disinfection, all poultry, other animals and their feeds must be removed from the premises. This includes emptying all troughs, racks, and other feeding and watering appliances. Remove all litter and droppings from floors, walls, and other surfaces occupied or traversed by other animals.

After disinfection, ventilate building, coops, and other closed spaces. Do not house poultry or animals or employ equipment until treatment has been absorbed, set or dried. After treatment, thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent and rinse with potable water before reuse.

ALL TREATED EQUIPMENT THAT WILL CONTACT FEED OR DRINKING WATER MUST BE RINSED WITH POTABLE WATER BEFORE REUSE.



* **VIRUCIDAL ACTIVITY** - This product, when used on environmental inanimate hard surfaces at 3.5 ounces per 5 gallons of water, with a 10 minute contact time, 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 Avian Influenza A (causative agent of an acute avian lower respiratory tract infection).

(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.

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

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard, non-porous surfaces add 3 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.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE 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. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, rubber gloves, and protective clothing. Harmful if swallowed. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

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 a poison control center or doctor for treatment advice.

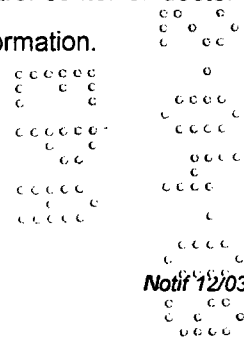
If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

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.



(Required for products supplied in containers 5 gallons or greater)

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.

