

1839 - 85

4/29/2010

1/8

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



Office of Pesticide Programs

Stepan Company
22 West Frontage road
Northfield, IL 60093

APR 29 2010

Attention: Thomas W. Isaac
Senior Regulatory Specialist

Subject: Aerosol Surface Disinfectant
EPA Registration No. 1839-85
Amendment Dated April 5, 2010

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

Proposed Amendment

- Addition of Marketing Phrase
- Addition of Bullets listing each organism claim
- Revision of the Dispenser Description
- Addition of Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus

Conditions

In the Agency's letter dated May 4, 2009, you were asked to change the pesticide disposal language to read:

Pesticide Disposal – Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two or more times.”

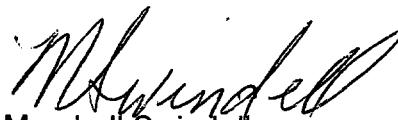
Page 2
EPA Registration No. 1839-85

General Comments

Submit two (2) copies of the final printed labels for our review. A stamped copy of the "accepted" product labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely



Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510P)

Enclosure

AEROSOL SURFACE DISINFECTANT

DISINFECTANT

MILDEWSTAT (on hard non-porous inanimate surfaces)

DEODORANT

AIR REFRESHENER

Kills 99.9% of Bacteria, Viruses & Fungi (*Staphylococcus aureus*, *Salmonella enterica*, *Pseudomonas aeruginosa*, *MRSA*, *Rhinovirus*, *Influenza A₂*, *Norovirus*, *Feline Calicivirus*, *Trichophyton mentagrophytes*)

Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu)

The following list of organisms is optional text:

- *Staphylococcus (S.) aureus*
- *Staphylococcus (S.) aureus MRSA*
- *Salmonella (S.) enterica*
- *Pseudomonas (P.) aeruginosa*
- *Influenza A₂ (H2N2)*
- *Norovirus*
- *Rhinovirus*
- *Feline Calicivirus*
- *Trichophyton (T.) mentagrophytes (Athlete's Foot Fungus)*

ACCEPTED
with COMMENTS
EPA Letter Dated: 1:
APR 29 2010

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides.....	0.1%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	0.1%
Isopropanol.....	53.0%
INERT INGREDIENTS	46.8%
Total	100.0%

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

1839-85

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side panels for additional precautionary statements.

EPA REG. NO. 1839-85
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road
Northfield, IL 60093

NET CONTENTS

Stepan Company
Northfield, IL 60093
EPA Reg. No. 1839-85

(page 1 of 6)

Amend 04/05/10

4
8

DIRECTIONS FOR USE

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

Aerosol Surface Disinfectant is designed for use in hospitals, nursing homes, hotels, schools, and homes, where disinfection and deodorization is of prime importance. When used as directed, this product is formulated to disinfect clean, inanimate, non-porous, hard surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, cabinets, tables, chairs, bed springs, door knobs, linen carts, hampers, wheel chairs, garbage pails, and telephones.

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.

This product can also be used as a room air deodorizer and refreshener.

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.

SURFACE DISINFECTION AND DEODORIZATION - For one-step disinfection, hold container six (6) inches from surface and spray area until completely wet, allowing the surface to remain wet for 10 minutes. For heavily soiled surfaces a pre-cleaning step is required.

(Aerosol Spray Can Label:) FOR USE IN (AN) AUTOMATIC DISPENSER UNITS (UNIT TRADE NAME) FOR (DOOR PUSH PLATE(S), (DOOR KNOB(s)), (and) (DOOR LEVER (S)) SURFACE DISINFECTION

- Remove cap and install in automatic aerosol dispensing unit (unit trade name). Dispenser unit (unit trade name) should be mounted 6"-12" above (bathroom) (door push plate) (door knob) (door lever) (and) (door surface) (high touch) surface. The unit (unit trade name) will provide a controlled spray that will wet accessible parts of the (door knob or lever) (and) (door push plate) surface. Allow to remain wet for 10 minutes for disinfection. Use only in a well ventilated area. Avoid inhaling spray mist or vapor. Avoid contact of spray mist or vapor with skin. The unit (unit trade name) will dispense every 15, 30 or 60 minutes. Each can (can trade name) will continue to release disinfectant for 7 to 30 days depending on the interval setting.

AIR DEODORIZER AND AIR REFRESHENER - Spray upwards to center of room for three (3) seconds.

FOR USE IN (AN) AUTOMATIC DISPENSER UNITS (UNIT) FOR (DEODORIZING) (REFRESHING) (AIR)

- Remove protective cap and install in automatic aerosol dispensing unit (unit trade name). Dispenser should be mounted 7 ft. from the floor and away from exposed foods. Position so that the concentrated spray will not come into direct contact with people, animals, food, animal feed, food processing surfaces, and/or solvent-sensitive surfaces (polished or varnished surfaces). Use only in a well ventilated area. Avoid inhaling spray mist or vapor. When the dispensing unit (unit trade name) is set for 24 hour operation and to disperse every 15 minutes, this can (container) contains 3900 controlled sprays that will last for approximately 30 days. When the dispensing unit (unit trade name) is set for 12 hour operation and to disperse every 15 minutes, this can (container) contains 3900 controlled sprays that will last for approximately 60 days.

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard, non-porous surfaces spray surface to be treated making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

ACCEPTED
with COMMENTS
EPA Letter Dated:

APR 29 2010

Stepan Company
Northfield, IL 60093
EPA Reg. No. 1839-85

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-85

Amend 04/05/10

BACTERICIDAL ACTIVITY - When used as directed, this product exhibits effective disinfectant activity against the organisms: Staphylococcus aureus (ATCC 6538), Salmonella enterica (ATCC 10708), Pseudomonas aeruginosa (ATCC 15442) and Methicillin Resistant Staphylococcus aureus (ATCC 33591) (MRSA) and meets all requirements for hospital use. This product kills 99.9% of bacteria on hard, non-porous inanimate surfaces.

VIRUCIDAL ACTIVITY - When used as directed, this product exhibits effective virucidal activity against the organisms: Rhinovirus (ATCC VR-284), Influenza A₂ (Japan/305/57)(H2N2), Norovirus (Norwalk Virus) and Feline Calicivirus.

(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.

FUNGICIDAL ACTIVITY - This product is fungicidal against the pathogenic fungi, Trichophyton mentagrophytes (Athlete's Foot Fungus) (ATCC 9533), when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, or other clean, non-porous, hard surfaces commonly contacted by bare feet.

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

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

KEEP OUT OF REACH OF CHILDREN. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

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 with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. 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.

(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.

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

APR 29 2010

Stepan Company
Northfield, IL 60093
EPA Reg. No. 1839-85

Under the Federal Insecticide,
Fungicide and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-85

Amend 04/05/10

6/8

PHYSICAL AND CHEMICAL HAZARD

Flammable! Contents under pressure. Do not use near fire, sparks, or flame. Do not puncture or incinerate container. Exposure to temperatures above 120°F may cause bursting.

STORAGE AND DISPOSAL

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

CONTAINER DISPOSAL – Do Not Puncture or Incinerate! Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions.

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

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

APR 29 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-85

7/8

The following installation information will be provided with the Automatic Dispenser Unit(s) for Surface Disinfection only: (Parentheses identify optional language)

Suggested Places for Use (Installation of Automatic Dispenser Unit)(Unit Trade Name): *(Any of the following may be listed)* Public Restroom (Exit Doors), Public Restroom Toilet Stall (Doors), Hospital Patient Room (Doors), School Classroom (Doors), Hotel Room (Doors), Dormitory (Dormitories)(Doors), Spa (Doors), Theater (Doors), Kitchen (Doors), Doors, Daycare facility (Doors)

Optimal Installation (Tips):

(The user will) Install the Automatic Dispenser Unit (Unit Trade Name) 6-12 inches above a (high touch) surface (door knob) (push plate). To properly disinfect, the Automatic Dispenser Unit (Unit Trade Name) should be centered such the (high touch) surface (door knob) (door lever) (push plate) is thoroughly wetted by the released disinfectant aerosol. (After 10 minutes,) Only the wet area contacted by the disinfectant aerosol will be disinfected (after 10 minutes.)

The Automatic Dispenser Unit (Unit Trade Name) can be manually set to spray at intervals of either 15, 30, or 60 minutes. The interval time is determined by the traffic in the location where the Automatic Dispenser Unit (Unit Trade Name) is installed. Depending on the surface (style of the door handle/knob/lever), place the Automatic Dispenser Unit (Unit Trade Name) in a position where the handle will receive the maximum amount of wetness. The spray is released in a conical pattern and the Automatic Dispenser Unit (Unit Trade Name) must be positioned correctly to achieve the most coverage. Once the position has been determined, affix the dispenser to the door with either the mounting tape or screws provided. See Installation Positioning (diagrams).

Additional Installation Instructions:

(Simply) Install the Automatic Dispenser Unit (Unit Trade Name) 6-12 inches above the (high touch) surface (e.g. door knob, door handle, door lever, push plate) and choose the interval time of 15, 30, 60 minutes between sprays. The unit will spray a light mist of an EPA registered disinfecting formula that will cover the (high touch) accessible area of the surface (handle)(knob)(lever)(plate). The quick drying formula will disinfect the wetted surface in 10 minutes. Each aerosol can (Spray Can Trade Name) will continue to release disinfectant for 7-30 days depending on the interval setting.

Additional Claims:

(Spray Can Trade Name) is a hospital disinfectant registered with the US EPA. The disinfectant has been shown to be effective against the following bacteria: Staphylococcus aureus, a common bacterial inhabitant of human skin, Salmonella enterica, a bacterium associated with foodborne illnesses, and Pseudomonas aeruginosa, a bacterial organism found in water, soil, and food. Methicillin Resistant Staphylococcus aureus (MRSA), Rhinovirus, Influenza A2 (H2N2), Norovirus, Feline Calicivirus, and Trichophyton (T.) mentagrophytes (Athlete's Foot Fungus).

(Spray Can Trade Name) has been shown to kill **COVID-19** and these important bacteria, viruses, and fungi (microorganisms):

ACCEPTED
with COMMENTS
EPA Letter Dated:

APR 29 2010

Stepan Company
Northfield, IL 60093
EPA Reg. No. 1839-85

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-85

Amend 04/05/10

8/8

Dispenser Description:

(Spray Can Trade Name) dispensing units are equipped with:

- Locked Housing which requires a key to open for replacement of the disinfectant spray or batteries.
- Motion sensor(s) which detect motion up to 50 centimeters in front of the housing and below the housing. If motion is detected up to 5 seconds prior to spraying, the unit does not dispense, a light flashes, and the device will not spray until it detects that there has been no movement in the zone for 5 seconds. The detection range cannot be manipulated.
- Power Indicator LCD which indicates the status of battery power. When the battery no longer has charge, the unit will display a flashing empty battery figure. The unit no longer has sufficient power to operate and only the LCD readout will continue to have power.

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

APR 29 2010

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-85**