

1839-224

06-15-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 15 2010

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

Subject: **SC QP-64**
EPA Registration Number 1839-224
Application Dated March 25, 2010
EPA Received Date March 26, 2010

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,
Drusilla Copeland
for Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: stamped label		CONCURRENCES					
SYMBOL							
SURNAME							
DATE							

SC QP-64

- (CLEANER) (CLEANS)
- (DISINFECTANT) DISINFECTS)
- (*VIRUCIDE) (*VIRUCIDAL)
- (DEODORIZER) (DEODORIZES)
- KILLS GERMS**
- Effective in the presence of 5% serum contamination
- Effective in the presence of 200 ppm hard water (as CaCO₃)
- Kills Pandemic 2009 H1N1-Influenza A virus (formerly called swine flu)

***Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella (choleraesuis) enterica*, MRSA, CA-MRSA, (*Escherichia coli*) (*E. coli*), (*Escherichia coli*) (*E. coli*) O157:H7, Influenza A, HIV-1

ACTIVE INGREDIENTS

Octyl decyl dimethyl ammonium chloride.....	1.728%
Dioctyl dimethyl ammonium chloride.....	0.864%
Didecyl dimethyl ammonium chloride.....	0.864%
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride	2.304%
OTHER INGREDIENTS	94.240%
Water, Hydrogen Peroxide, Amine Oxide, Phosphoric Acid	
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

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.

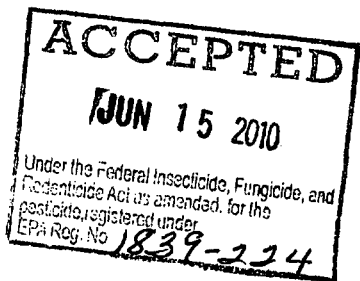
If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

(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.

See (side) (back) (left) (right) panels for additional precautionary statements.

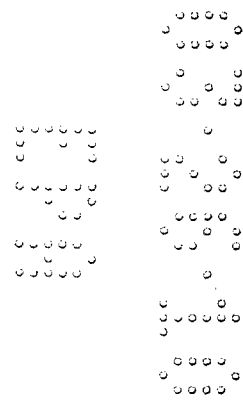


EPA REG. NO. 1839-224
EPA EST. NO. 1839-IL-01

STEPAN COMPANY

22 West Frontage Road
Northfield, IL 60093

NET CONTENTS



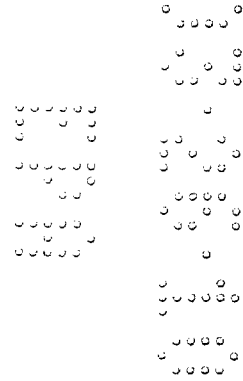
This product can be used (as a disinfectant in) (to disinfect) the following areas:

- Bathrooms
- Kitchens
- Day Care Centers
- Nurseries
- Athletic Facilities
- Airports
- Cruise Ships
- Casinos
- Office Buildings
- Colleges
- Correctional Facilities
- Dressing Rooms
- (Exercise Facilities) (Gyms) (Health Clubs)
- Factories
- (Food service establishments) (restaurants) (bars) (catering establishments) (taverns)
- (Lodging establishments) (Hotels) (Motels)
- Institutional Facilities
- Institutions
- Locker Rooms
- Motels
- Correctional Facilities
- Public Facilities
- Public Restrooms
- Retail facilities
- Schools
- Showers and Bath areas
- Boats
- Buses Trailers
- Universities
- Warehouses

This product can be used in the following hospital/ healthcare settings:

- Dental Offices
- Health Care Facilities
- Hospitals
- Medical Offices
- Nursing Homes

(This product) (product name) is a quaternary ammonium chloride based disinfectant cleaner containing hydrogen peroxide stabilized with phosphoric acid and an amine oxide surfactant to aid cleaning.



This product can be used on the following washable, hard, inanimate, non-porous surfaces:

- Aluminum
- Bathroom fixtures – **NOTE: DO NOT USE ON BRASS**
- Bathtubs
- Cabinets
- Ceilings
- Chairs
- Chrome
- Counters (Countertops)
- Desks
- Doorknobs – **NOTE: DO NOT USE ON BRASS**
- Faucets – **NOTE: DO NOT USE ON BRASS**
- Floors
- Foot Spas
- Garbage Cans
- Highchairs
- Mirrors
- Showers
- Shower Stalls
- Sinks
- Stainless Steel
- Tables
- Toilets
- Toilet Bowls
- Tubs (Fiberglass)
- Tiles, glazed
- Urinals
- Vinyl
- Walls
- Windows
- Whirlpool baths

and other hard nonporous inanimate surfaces made of:

- Glazed ceramic
- Glazed porcelain
- Metal
- Plastic
- Sealed Stone
- Stainless Steel

DIRECTIONS FOR USE:

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

This product contains hydrogen peroxide. This product must not be mixed or stored with products containing ammonia and bleach, or other reducing and oxidizing agents.

Contact with metals, metal ions, wood dust, or wood shavings may cause product decomposition.

(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 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 normally sterile areas of the body.

OR

This product is not for use on critical or semi-critical medical device surfaces.

Bactericidal (Activity): When use as directed at 2 ozs. per gallon of water (or equivalent dilution) (1:64), (this product) (product name) is exhibits effective disinfectant activity against: *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (Staph) (ATCC 6538), *Salmonella (choleraesuis) enterica* (Salmonella) (ATCC 10708), Methicillin resistant *Staphylococcus aureus* (MRSA) (ATCC 33593), Community Associated Methicillin resistant *Staphylococcus aureus* (CA-MRSA), Genotype USA 300, Community Associated Methicillin resistant *Staphylococcus aureus* (CA-MRSA), Genotype 400, *Escherichia coli (E. coli)* (ATCC 11229), *Escherichia coli (E. coli)* O157:H7 (ATCC 43895) at 10 minutes contact time.

***Virucidal Activity:** When used as directed at 2 ozs per gallon of water (or equivalent dilution) (1:64), (this product) (product name) is effective against Influenza Type A (ATCC VR-544) with a 10 minute contact time and Human Immunodeficiency Virus type 1 (Strain HTLV-III_B) (HIV-1) with a 1 minute contact time.

(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.

***This product kills HIV-1 in 1 (one) minute on pre-cleaned environmental surfaces/objects previously soiled with blood/ body fluids** in settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or bodily 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 ON SURFACES/ OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: Disposable protective gloves, gowns, facemasks, or eye coverings as appropriate must be worn during all cleaning of body fluids, blood and decontamination procedures.

Cleaning Procedures: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

Contact Time: Allow surface to remain wet for 1 minute to kill HIV-1 and 10 minutes for all other bacteria and viruses claimed.

Disposal of Infectious Material: Blood and other body fluids must be autoclaved and disposed of in accordance with Federal, State and local regulations for infectious waste disposal.

(THIS PRODUCT) (PRODUCT NAME) IS AN EFFECTIVE BACTERICIDE AND *VIRUCIDE WHEN DILUTED IN HARD WATER UP TO A MAXIMUM OF 200 PPM HARDNESS (AS CaCO₃) IN THE PRESENCE OF ORGANIC SOIL LOAD (5% BLOOD SERUM).

DISINFECTING, CLEANING and DEODORIZING DIRECTIONS: To disinfect hard non-porous inanimate surfaces, dilute 2 ozs. of concentrate per gallon of water (1:64 dilution) (or equivalent dilution). Remove heavy soil deposits from surfaces. Apply to surfaces using a cloth, mop, sponge, or coarse trigger sprayer. Spray 6-8 inches from surface to be treated, thoroughly wetting the surface. Allow surface to remain wet for 10 minutes. Rub with brush, sponge, or cloth. Do not breathe spray. Wipe area with a clean cloth or allow to air dry.

DISINFECTING and CLEANING OF WHIRLPOOLS AND FOOTBATHS: To remove body oils, dead tissue, soil, and all other buildups or organic matter on inanimate surfaces after using the footbath, drain the water and thoroughly clean all hard, nonporous surfaces with soap or detergent, then rinse with water. Wet surfaces with a use-solution of 2 ozs. per gallon of water (1:64 dilution) (or equivalent dilution). Apply solution to exposed surfaces with a cloth, mop, sponge or sprayer. For spray applications, use a coarse spray device. Do not breathe spray. Brush or swab thoroughly and allow solution to stand for 10 minutes. After the bath has been thoroughly disinfected, rinse all surfaces with clean fresh water. Whirlpools and footbaths should not be used until treatment has set and dried.

DISINFECTING TOILET BOWLS and URINALS:

Swab bowl with brush to remove heavy soil prior to cleaning or disinfecting. Clean by applying use-solution around the bowl and up under the rim. Stubborn stains may require brushing. To disinfect, first remove or expel the residual bowl water over the inner trap. Thoroughly wet the (bowl) (urinal) (bowl and urinal) surfaces with a use-solution of 2 ozs. per gallon of water (1:64 dilution) (or equivalent dilution). Swab the bowl completely using a scrub brush or mop, making sure to get under rim. Let stand for 10 minutes. Rinse by flushing.

DISINFECTING FOOD SERVICE ESTABLISHMENT (RESTAURANT) FOOD CONTACT SURFACES: countertops, appliances, tables, wet the surfaces with a use-solution of 2 ozs. per gallon of water (1:64 dilution) (or equivalent dilution). For heavily soiled areas, a pre-cleaning step is required. Apply solution with a cloth, sponge or hand pump trigger sprayer to thoroughly wet all surfaces. Allow surfaces to remain wet for 10 minutes, then remove excess liquid and rinse the surfaces with potable water. (This product) (Product name) cannot be used to clean the following food contact surfaces: utensils, glassware and dishes.

CARPET CLEANING (SPOTTER): For coffee as well as other water based stains, apply a small amount of (this product) (product name) to the stain. Agitate with a bone scraper and let stand for 3-5 minutes. Blot dry and rinse with clean water. Repeat as needed until the stain is completely removed. Always test first in an inconspicuous area. To test: Apply a small amount, press with an absorbent white cloth for 10 seconds and see if there is any dye transfer.

CARPET CLEANING (PRE-SPRAY): Dilute at 2 ozs. per gallon of water (1:64 dilution) (or equivalent dilution). Let stand for 5-10 minutes. Extract carpet. Allow to dry before allowing foot traffic on carpet.

GLASS CLEANING: Dilute 1 oz. of product per gallon of water (1:128 dilution) (or equivalent dilution). Spray onto glass surface. Use through a coarse hand pump trigger sprayer device. Do not breathe spray. Wipe dry with an absorbent cloth or towel.

CLEANING/DEODORIZING DIRECTIONS: For cleaning and deodorizing, dilute 2 ozs. of concentrate per gallon of water (1:64). Cleaning may be accomplished with a clean mop, sponge, squeegee, wet vacuum system or a trigger spraying device. Spray 6-8 inches from the surface to be treated, thoroughly wetting the surface. After cleaning, remove suspended soils with a clear water rinse, vacuum pick up, or by wiping with a clean mop, sponge, squeegee, or cloth or allow to air dry. Do not breathe spray.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or inhaled. Do not get in eyes, on skin or on clothing. Wear eye protection (goggles, safety glasses with side shields, or face shield). Wear coveralls worn over long-sleeved shirts and long pants, chemical resistant gloves, socks, and chemical resistant footwear. Avoid contamination of food. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

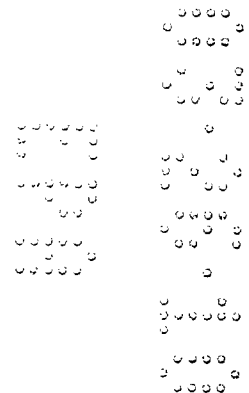
PHYSICAL OR CHEMICAL HAZARDS

Combustible. This product contains an oxidizer. Do not store near heat, flame, or in direct sunlight. Avoid storage at elevated temperatures. Do not store near wood shavings, dust or similar combustible materials.

(For containers 5 gallons or more, the following Environmental Hazard Statement must be used in addition to the Storage and Disposal Statements)

ENVIRONMENTAL HAZARDS

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 of Regional Office of the EPA.



STORAGE AND DISPOSAL

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

CONTAINER STORAGE – Keep product under locked storage, inaccessible to children.

(for products with industrial, institutional and commercial use sites)

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.

