

1839-176

AUG 4 2010

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

Subject: **Liquid-Pak Neutral Disinfectant Cleaner**
EPA Registration Number 1839-176
Notification Dated August 3, 2010
EPA Received Date August 3, 2010

Dear Mr. Isaac:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:

- Add labeling claims against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/09

General Comments:

Based on a review of the material submitted, the following comment apply:

The notification is acceptable. A copy has been inserted in your file for future reference.

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 (7510F)

SYMBOL							
SURNAME							
DATE							



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1839-176	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Liquid-Pak Neutral Disinfectant Cleaner	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: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____

Resubmission in response to Agency letter dated _____ "Me Too" Application.

Notification - Explain below. 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:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.794 oz. No. per container multiple	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>Water Soluble Film</u>
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3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container

5. Location of Label Directions
 On Label
 On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
 Lithograph
 Paper glued
 Stenciled Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Thomas W. Isaac	Title Sr. Regulatory Specialist	Telephone No. (Include Area Code) (847) 501-2309
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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 or both under applicable law.

8. Date Application Received (Stamped)

2. Signature <i>Thomas W. Isaac</i>	3. Title Sr. Regulatory Specialist
4. Typed Name Thomas W. Isaac	5. Date Aug 3, 2010

Stepan

Stepan Company

Northfield, Illinois 60093
Telephone 847 446 7500



“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: August 3, 2010

Stepan

pan Company

Northfield, Illinois 60093
Telephone 847 446 7500



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August 3, 2010

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: Liquid-Pak Neutral Disinfectant Cleaner
EPA Reg. No. 1839-176

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

172-10-TI-EPA-1839-176

Liquid-Pak Neutral Disinfectant Cleaner

CLEANER
DETERGENT
* VIRUCIDE

DISINFECTANT
DEODORIZER

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

ACTIVE INGREDIENTS

Octyl decyl dimethyl ammonium chloride	15.24%
Dioctyl dimethyl ammonium chloride	7.62%
Didecyl dimethyl ammonium chloride	7.62%
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride.....	20.32%
INERT INGREDIENTS	<u>49.20%</u>
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panels for additional precautionary statements.

EPA REG. NO. 1839-176

EPA EST. NO. 1839-IL-01

STEPAN COMPANY

22 W. Frontage Rd.
Northfield, IL 60093

NET CONTENTS

Water Soluble Packets, each containing 0.794 ounces of product

Water Soluble Packets, each containing 0.0993 ounces of product

NOTIFICATION
Date Reviewed: 3/4/10
Reviewed By: APC

DIRECTIONS FOR USE

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

This product is a phosphate-free formulation designed to provide effective cleaning, deodorizing, and disinfection for hospitals, nursing homes, hotels, schools, and restaurants where housekeeping is of prime importance in controlling cross-contamination from treated surfaces.

This product, when used as directed, is formulated to disinfect hard non-porous inanimate environmental surfaces such as floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, and cabinets. For larger areas such as operating rooms and patient care facilities, 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 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.

This product is formulated to a neutral pH and will not dull high-gloss floor finishes with repeated use.

This product is a water-soluble packet. Follow label dilution instructions by dropping packet directly into water. Do not remove packets before use. Store in cool dry place. Do not handle packets with wet hands.

GENERAL CLEANING & DEODORIZATION – Apply product to soiled area with a mop, cloth, sponge, or hand pump trigger sprayer. Product must be diluted as indicated in the DISINFECTION section. Thoroughly wet soiled surface and scrub as necessary. Rinse surface with potable water and wipe dry with a dry paper towel or lint-free cloth.

DISINFECTION - To disinfect inanimate, hard, non-porous surfaces use the appropriate size premeasured packet.

<u>Packet Size</u>	<u>Net Weight</u>	<u>Number of Packets</u>	<u>Dilution</u>
Small	0.0993 ounce	1	Quart
Large	0.794 ounce	1	2 gallons
Large	1.59 ounce	2	4 gallons

Stir gently to form a uniform solution. 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.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

(Choose one of the following Toilet Bowl paragraphs):

TO DISINFECT TOILET BOWLS: Remove gross filth or soils from surfaces with bowl brush prior to disinfection. Add 2 small, premeasured packets (0.0993 ounce each) or 1 large, premeasured packet (0.794 ounce) of product to bowl water. Brush or 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.

(Optional): **TO DISINFECT TOILET BOWLS:** Remove gross filth or soils from surfaces with bowl brush prior to disinfection. Remove or expel over the inner trap the residual bowl water. Make a dilute solution by dissolving one (1) packet in one (1) quart of water. If a larger quantity is desired, refer to dilution chart above. Apply use 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. Brush or 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 RESTAURANT FOOD CONTACT SURFACES: countertops, appliances, tables, add the appropriate size premeasured packet as indicated in the DISINFECTION section. Apply solution with a cloth, sponge, or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow the surface to remain wet for 10 minutes, then remove excess liquid and rinse the surface with potable water. This product cannot be used to clean the following food contact surfaces: utensils, glassware and dishes.

BACTERICIDAL ACTIVITY – When diluted as indicated in the DISINFECTION section, this product demonstrates effective disinfectant activity against the organisms: Pseudomonas aeruginosa, Salmonella choleraesuis, Staphylococcus aureus, Methicillin resistant Staphylococcus aureus (MRSA), Vancomycin intermediate resistant Staphylococcus aureus (VISA) and Vancomycin resistant Enterococcus faecalis (VRE).

* **VIRUCIDAL ACTIVITY** - This product when used on environmental, inanimate hard non-porous surfaces add one large (0.794 ounce) packet per 2 gallons of water or one small packet (0.0993 ounce) per quart of water exhibits effective virucidal activity against HIV-1, Hepatitis B virus (HBV), Hepatitis C virus (HCV), SARS associated Coronavirus, Herpes Simplex Type 1 (causative agent of fever blisters), Herpes Simplex Type 2 (genital) and Influenza A₂/Hong Kong.

(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.

KILLS HIV-1, HBV and HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings (Hospitals, Nursing Homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body 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), Hepatitis B virus (HBV) and Hepatitis C virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV and HCV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE AND VIRUCIDE IN WATER UP TO 400 PPM HARDNESS (AS CaCO₃) 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 skin burns and irreversible eye damage. May be fatal if absorbed through skin or swallowed. Do not get in eyes, on skin or on clothing. Wear protective goggles or face shield, protective clothing and rubber (or chemical resistant) gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash clothing 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 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 product supplied in containers of 5 gallons or greater.)

ENVIRONMENTAL HAZARDS

This pesticide 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 STORAGE/DISPOSAL: Store in an area inaccessible to children. Container: Tightly close lid between uses to retain moisture. Non-refillable container. Do not reuse or refill this container. Offer empty container for recycling if available or discard 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.

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