

APR 7 2005

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

Subject: Detergent Disinfectant Pump Spray  
EPA Registration no. 1839-83  
Application Date: 11/18/04  
Receipt Date: 11/19/04

Dear Mr. Isaac:

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

Label additions and revisions

### EFFICACY

1. The proposed label claims that the product is efficacious against Norwalk virus and Feline calicivirus. The claim against Norwalk virus is currently unacceptable. Testing to support Norwalk claims was conducted using Feline calicivirus as a surrogate. As it currently stands, a Norwalk virus testing protocol is still under development by the Agency.

Following Agency approval of the Norwalk virus testing protocol, addition of the Norwalk virus claim to the product label may be acceptable if the Agency determines that the protocol employed in the submitted studies (MRIDs 464086-04 and 464199-01) contains all of the necessary components of the final Agency protocol; as posted on the Agency web site. (In the interim, you must delete any reference to the Norwalk virus from the label until testing by the Agency is completed).

2. The proposed label makes disinfectant claims against the following organisms and the respective contact times necessary for their removal. These claims are supported by the submitted data and are acceptable.

Clostridium difficile*	1 minute
Pseudomonas aeruginosa	3 minutes
Staphylococcus aureus	3 minutes

Escherichia coli

CONCURRENCES

MBOL	7510C						
SURNAME	T. Isaac						
DATE	4-3-05						

Escherichia coli 0157:H7	3 minutes
Listeria monocytogenes	3 minutes
Yersinia enterocolitica	3 minutes
Enterococcus faecium	3 minutes
Corynebacterium ammoniagenes	3 minutes
Salmonella typhi	3 minutes
Streptococcus pyogenes (Necrotizing Fascitis, Group A)	3 minutes
Staphylococcus aureus (MRSA)	3 minutes
Enterococcus faecalis (VRE)	3 minutes
Staphylococcus aureus (VISA)	3 minutes
Mycobacterium tuberculosis	5 minutes
Feline calicivirus	30 seconds
Hepatitis A virus	10 minutes
Human coronavirus**	10 minutes
Rabies virus	10 minutes

\*Effectiveness against *Clostridium difficile* refers to vegetative cells only, and not spores of the organism.

\*\*Note: Effectiveness against Human coronavirus in no way implies efficacy against the SARS virus and the applicant must make no such claims.

3. Instructions for disinfection indicate a contact time of 3 minutes with the exception of bloodborne pathogens. This is unacceptable. The contact time listed for tuberculocidal activity is 5 minutes. You must either increase the general contact time for disinfectant to 5 minutes or add a disclaimer that for TB treatment, the surface is to remain wet for 5 minutes.

4. The applicant's proposal to list on the product label VA Medical Center Clinical Isolate No. 04001 as "*Streptococcus pyogenes* (Necrotizing Fascitis-Flesh Eating Group A)" is unacceptable. You must list this organism as "*Streptococcus pyogenes* (Necrotizing Fascitis-Group A)". The words "Flesh Eating" must not appear on the product label. (Please delete from the label).

### **LABELING**

- As mentioned in (3) above, you must change the contact time for disinfectant in all paragraphs to 5 minutes (and 10 minutes for Bloodborne pathogens) , or indicate that the contact time is 3 minutes and that for *Mycobacterium tuberculosis* the surface should remain wet for 5 minutes.
- Under the heading of Bactericidal Activity (first paragraph), *Streptococcus pyogenes* (Necrotizing Fascitis-Flesh Eating- Group A), (ATCC 19615)" must be changed to read "*Streptococcus pyogenes* (Necrotizing Fascitis-Group A), (VA Medical Ctr. Isolate 04001)." The strain tested was not ATCC strain number 19615 as indicated on the label: it was a clinical isolate (designated No. 04001) from the Department of Veterans Affairs Medical Center in Louisville, Kentucky. In addition, as indicated in (4) above, the words

"Flesh Eating" are not to appear on the label.

- Under the heading of Antibiotic Resistant....(second paragraph), change "(CDC Strain)" to read "(CDC Isolate 99287)" so as to indicate the actual strain tested.

**TOXICITY**

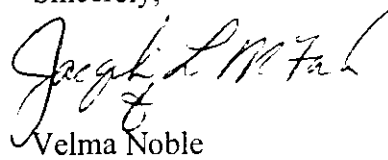
Toxicity profile is acceptable. See enclosed review.

**GENERAL COMMENTS**

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Zenobia Jones at (703) 308-6198.

Sincerely,

A handwritten signature in cursive script, appearing to read "Joseph L. Noble", is written over the printed name "Velma Noble".

Velma Noble

Product Manager 31

Regulatory Management Branch 1

Antimicrobial Division (7510C)

# DETERGENT DISINFECTANT PUMP SPRAY

- CLEANER
- DEODORIZER
- DISINFECTANT
- \*VIRUCIDE
- TUBERCULOCIDAL
- MILDEWSTAT (on hard inanimate surfaces)
- FUNGICIDE (against pathogenic fungi)
- Orange Scent, Lemon Scent, Fresh Scent, Citrus Scent
- Ready-To-Use (RTU or R-T-U) Disinfectant Spray
- Eliminates Odors
- Cleans and Deodorizes in One Easy Step
- Cuts (Tough) Grease and Grime (without Scrubbing)
- Kills 99.9% of Germs
- Kills 99.9% of Bacteria
- Kills 99.9% of Household Bacteria
- Meets OSHA Bloodborne Pathogen Standard for HIV, HBV, HCV & HAV
- For Use in Animal Housing Facilities (Public Restrooms) (as a Non-Acid Bowl (& Bathroom) Disinfectant Cleaner)

ACCEPTED  
with COMMENTS  
in EPA Letter Dated  
APR - 7 2005  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 1839-83

## ACTIVE INGREDIENTS

n-Alkyl (60% C<sub>14</sub>, 30% C<sub>16</sub>, 5% C<sub>12</sub>, 5% C<sub>18</sub>)  
dimethyl benzyl ammonium chlorides ..... 0.105%  
n-Alkyl (68% C<sub>12</sub>, 32% C<sub>14</sub>) dimethyl  
ethylbenzyl ammonium chlorides ..... 0.105%

**INERT INGREDIENTS** ..... 99.790%  
Total ..... 100.000%

KEEP OUT OF REACH OF CHILDREN

## CAUTION

See side (back) panels for additional precautionary statements.

EPA REG. NO. 1839-83  
EPA EST. NO. 1839-IL-01

**STEPAN COMPANY**  
22 West Frontage Road  
Northfield, IL 60093

NET CONTENTS

U.S. Patent No. 5,444,094

Detergent Disinfectant Pump Spray (or this product or product name) is designed specifically as a general (non-acid) (ready-to-use) (non-abrasive) cleaner and disinfectant for use in homes, hospitals, nursing homes, patient rooms, operating rooms, ICU areas, shower rooms, locker rooms, public restrooms, schools, food processing plants, food service establishments (restaurants) (commercial kitchens), transportation terminals, office buildings, manufacturing facilities, lodging establishments, retail businesses, veterinary clinics, pet shops, animal life science laboratories and athlete/recreational facilities where housekeeping is of prime importance in controlling the hazard of cross contamination. It is formulated to disinfect hard, non-porous, inanimate environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, chrome, brass, copper, laminated surfaces, baked enamel surfaces, bathrooms, shower stalls, bathtubs, and cabinets. For plastic and painted surfaces, spot test on an inconspicuous area before use. May be used in the kitchen on counters, sinks, appliances, and stove-tops. A rinse with potable water is required for surfaces in direct contact with food. (In addition), (this product or product name) deodorizes those areas that generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, basements, restrooms and other areas which are prone to odors caused by microorganisms.

**(Additional Claims, Uses & Applications):**

- When used as directed, (this product or product name) (contains 2100 ppm of active germicide making it) (is) highly effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, antibiotic resistant bacteria, viruses, fungi, mold and mildew.)
- (This product or product name) is a one-step (hospital-use) germicidal (disinfectant) cleaner and deodorant (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting (deodorizing) (and controlling mold and mildew on) (of) hard, non-porous inanimate surfaces. Quickly removes dirt, grime, mold, mildew, food residue, blood and other organic matter commonly found in hospitals (in health care facilities) (on medical surfaces). It (also) eliminates odors leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.
- **Animal Housing Facilities:** (This product or product name) removes dirt, grime, mold, mildew, blood, urine, fecal matter and other common soils found in animal housing facilities, grooming facilities, kennels, pet stores, veterinary clinics, laboratories or other small animal facilities. It (also) eliminates odors leaving surfaces smelling clean and fresh.
- It cleans, disinfects and deodorizes hard, non-porous inanimate surfaces in one step. Its non-abrasive formula is designed for use on (Use daily on) (Use daily to clean and disinfect) hard, non-porous inanimate surfaces: plated or stainless steel, aluminum, chrome, glazed porcelain, glazed tile, laminated surfaces associated with floors, walls, countertops, cages, crates, kennels, and animal equipment found in animal housing facilities.
- **Public Restrooms:** (This product or product name) is a one-step disinfectant cleaner and deodorant (odor-counteractant) (odor-neutralizer) designed for general cleaning, (and) (disinfecting) (deodorizing) (and controlling mold and mildew) on hard, non-porous inanimate surfaces.
- It cleans, disinfects and deodorizes surfaces by killing odor-causing microorganisms and prevents (inhibits) (controls) the growth of mold and mildew. Its non-abrasive formula is designed for use on (restroom surfaces): glazed ceramic (restroom surfaces), glazed porcelain, chrome, stainless steel and plastic surfaces associated with floors, walls, fixtures, toilets, urinals, sinks, shower rooms and locker rooms.
- **Non-Acid Bowl (& Bathroom) Disinfectant Cleaner:** (This product or product name) is (also) a (ready-to-use) non-acid (bowl and) bathroom cleaner that cleans, disinfects and deodorizes in one easy step. It cleans, disinfects and deodorizes toilet bowls, urinals, rims, sinks, sink basins, faucets, tubs, glazed tiles, glazed ceramic, glazed porcelain, chrome, stainless steel, and all non-porous inanimate surfaces found in the bathroom (restroom) (in the presence of organic soil).
- It eliminates odors, leaving bathrooms (restrooms) smelling clean and fresh. Use where odors are a problem. It cleans, disinfects, and deodorizes surfaces by killing odor-causing microorganisms and prevents (inhibits) (controls) the growth of mold and mildew. Its non-abrasive formula is designed for use (Use it daily) on (restroom surfaces): glass, glazed ceramic (restroom surfaces), glazed tile, glazed porcelain, chrome, stainless steel, and plastic surfaces associated with floors, walls, fixtures, toilets, urinals, sinks, shower rooms, and locker rooms.

## DIRECTIONS FOR USE

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

*(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 critical or semi-critical medical device surfaces.

*(Optional Directions for Product Supplied in Refill Bottles)*

Fill or refill the X ozs. (this product or product name) spray bottle with (this product or product name) refill. Pour product into spray bottle over sink or tub basin.

**DISINFECTION, DEODORIZING AND CLEANING** - Remove gross filth or heavy soil prior to application of the product. Hold container six to eight inches from surface to be treated. Spray area until it is covered with the solution. Allow product to penetrate and the surface to remain wet for 3 minutes (for Bloodborne Pathogens: HIV-1, HBV, HCV, and HAV allow surface to remain wet for 10 minutes). No scrubbing is necessary. Wipe off with a clean cloth, mop or sponge. The product will not leave grit or soap scum.

**One-step cleaning and disinfection of toilet bowls and urinals:** Remove water from bowl by forcing water over trap with a swab mop applicator. Press swab mop against side of the bowl to remove excess water from applicator. Apply 1 to 2 ounces of (this product or product name) evenly, allowing sufficient time for product to cover entire surface of bowl for maximum cleaning. Swab bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 3 minutes (for Bloodborne Pathogens: HIV-1, HBV, HCV, and HAV allow surface to remain wet for 10 minutes) and flush.

**To disinfect food processing premises:** floors, walls and storage areas, hold container six to eight inches from the surface to be treated and spray area until it is covered with the solution. Allow (product or product name) to penetrate and remain wet for 3 minutes (for Bloodborne Pathogens: HIV-1, HBV, HCV, and HAV allow surface to remain wet for 10 minutes). Wipe off with a clean cloth, mop or sponge and thoroughly rinse all surfaces in the area with potable water. Heavily soiled areas must be pre-cleaned before using this product. Food products and packaging materials must be removed or carefully protected prior to using this product.

**To disinfect food service establishment food contact surfaces:** countertops, appliances, tables, hold container six to eight inches from the surface to be treated and spray area until it is covered with the solution. Allow (product or product name) to penetrate and remain wet for 3 minutes (for Bloodborne Pathogens: HIV-1, HBV, HCV, and HAV allow surface to remain wet for 10 minutes). Wipe off with a clean cloth, mop or sponge and thoroughly rinse all surfaces in the area with potable water. Heavily soiled areas must be pre-cleaned before using this product. Do not use on eating utensils, glassware and cookware.

**Disinfection of animal quarters and kennels:** For disinfection of pre-cleaned animal quarters and kennels, apply (this product or product name). Remove all animals and feed from premises. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate the surfaces with the disinfecting solution for a period of 10 minutes. Ventilate building and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. All treated equipment that will contact feed or drinking water must be rinsed with potable water before reuse.

Using approved AOAC test methods (under Good Laboratory Practices, [GLPs]), in the presence of 5% blood serum and a 3 minute contact time, unless otherwise noted, (this product or product name) kills the following organisms on hard non-porous inanimate surfaces:

**BACTERICIDAL ACTIVITY (BACTERIA):**

*Pseudomonas aeruginosa*, (ATCC 15442)  
*Staphylococcus aureus*, (ATCC 6538)  
*Salmonella choleraesuis*, (ATCC 10708)  
*Escherichia coli*, (ATCC 11229)  
*Escherichia coli* O157:H7, (ATCC 43895)

*Listeria monocytogenes*, (ATCC 35152)  
*Yersinia enterocolitica*, (ATCC 23715)  
*Enterococcus faecium*, (ATCC 6569)  
*Corynebacterium ammoniagenes*, (ATCC 6871)  
*Salmonella typhi*, (ATCC 6539)  
*Streptococcus pyogenes* (Necrotizing Fasciitis—  
 Group A), (ATCC 19615)

**ANTIBIOTIC-RESISTANT (STRAINS OF) (ANTIBIOTIC-RESISTANT BACTERICIDAL ACTIVITY):**

*Methicillin resistant Staphylococcus aureus* (MRSA), (ATCC 33593)  
*Vancomycin resistant Enterococcus faecalis* (VRE), (ATCC 51575)  
*Vancomycin intermediate resistant Staphylococcus aureus* (VISA), (CDC Strain)

(This product or product name) exhibits effective disinfectant activity against *Clostridium difficile* vegetative form, ATCC 9689, when the treated surface is allowed to remain wet for 1 minute (60 seconds).

**TUBERCULOCIDAL ACTIVITY** – (This product or product name) exhibits disinfectant efficacy against *Mycobacterium tuberculosis* (BCG) in 5 minutes at 20 degrees Centigrade when used as directed on previously cleaned hard non-porous inanimate surfaces.

**\*VIRUCIDAL ACTIVITY** – (This product or product name) kills on hard, non-porous inanimate surfaces when allowed to remain wet for a 10 minute contact time against:

HIV-1 (associated with AIDS)	Poliovirus Type 1
Hepatitis B Virus (HBV)	
Hepatitis C Virus (HCV)	Canine Parvovirus
Hepatitis A Virus (HAV)	Bovine Viral Diarrhea Virus (BVDV)

(This product or product name), when used on environmental, inanimate hard surfaces exhibits effective virucidal activity against [REDACTED] *Feline Calicivirus*, when the treated surface is allowed to remain wet for 30 seconds).

(This product or product name), when used on environmental, inanimate hard surfaces exhibits virucidal activity against *Human Coronavirus* when the treated surface is allowed to remain wet for 2 minutes.

(This product or product name), when used on environmental, inanimate hard surfaces exhibits virucidal activity against *Rabies Virus* when the treated surface is allowed to remain wet for 30 seconds.

*(The following statements must be used for Bloodborne Pathogens: HIV-1, HBV, HCV, and HAV:)*

**KILLS HIV-1, HBV, HCV, AND HAV 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), Hepatitis C Virus (HCV), and Hepatitis A Virus (HAV).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV, HCV and HAV ON 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.

**FUNGICIDAL ACTIVITY** – (This product or product name) is fungicidal against the pathogenic fungus, *Trichophyton mentagrophytes* (Athlete's Foot Fungus), when used with a 10 minute contact time on clean, non-porous, hard surfaces as found in bathrooms, shower stalls, locker rooms, or other areas commonly contacted by bare feet.

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

**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.

## 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 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 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 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 DISPOSAL** – *Plastic Containers:* Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and 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.

*Container Disposal for Refill Spray Bottle:* Do not reuse empty spray bottle except with refill bottle, otherwise discard in trash. Do not reuse empty refill bottle. Wrap refill bottle and 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.