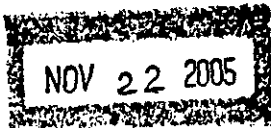


1839-175

11/22/2005

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

Subject: Solvent Free Detergent Disinfectant pump Spray  
EPA Registration No. 1839-175  
Application Date: 7/8/05  
Receipt Date: 7/13/05

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:

- . Removing the "Limited Disinfectant Claim"
- . Adding Hospital claims
- . Adding several organism (bacteria and viruses)
- . Adding Non Food Contact Surface Sanitization claims
- . Adding miscellaneous marketing claims, qualifiers and disclaimers

**EFFICACY**

1. The proposed label claim that the product, Solvent Free Detergent Disinfectant Pump Spray, is an effective disinfectant on hard, non-porous surfaces against the following microorganisms in the presence of a 5% serum load for a contact time of 10 minutes:

Staphylococcus aureus	Escherichia coli 0157:H7
Pseudomonas aeruginosa	Streptococcus pyogenes
Herpes simplex virus 2	Influenza A2 Hong Kong

Data provided support these claims

**Note:** The label claim effectiveness against Influenza A2 Hong Kong. Efficacy studies were conducted against Influenza A2 virus (Strain A/2/Japan/305/57). You may want to change "Influenza A2 Hong Kong" to read "Influenza A2 virus".

2. The proposed label claims that the product, Solvent Free Detergent Disinfectant Pump Spray, is an effective sanitizer for use on non-food contact surfaces at full strength in the presence of a 5% serum load against ~~the following~~ **CONCURRENCES** microorganisms with a 5 minute

SYMBOL	75100						
SURNAME	T. Isaac						
DATE	11-29-05						

contact time.

Campylobacter jejuni  
Staphylococcus aureus  
Listeria monocytogenes

Klebsiella pneumoniae  
Escherichia coli 0157:H7

Data provided support these claims. One pages 2 and 3, you should change "Camphylobacter jejuni" to read "Camphylobacter jejuni".

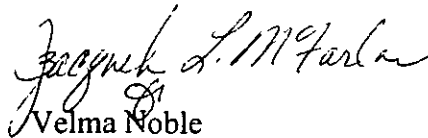
- 3. On page 1, the proposed label claims that the product, Solvent Free Detergent Disinfectant Pump Spray, is an effective sanitizer against Salmonella choleraesuis with a 5-minute contact time. You did not provide data to support the claim. You must delete this reference to Salmonella choleraesuis.
- 4. The proposed label indicates that the product may be used on the fiberglass surfaces. Fiberglass is a porous surface. You must delete this general reference to fiberglass. You may indicate on the product label that the product may be used on fiberglass bathtubs or sealed fiberglass surfaces.

**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,



Velma Noble  
Product Manager 31  
Regulatory Management Branch 1  
Antimicrobial Division (7510C)

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(Use for consumer as well as institutional label.)

# SOLVENT FREE DETERGENT DISINFECTANT PUMP SPRAY

CLEANER  
DEODORIZER  
ALL PURPOSE CLEANER  
KILLS GERMS \*\*  
KILLS 99.9% OF (SOME) BACTERIA\* (requires disinfection use directions)  
KILLS 99.9% OF BACTERIA\* in 5 minutes (requires sanitizer use directions)  
CLEANS STREAK-FREE  
SANITIZER—Non-Food Contact Surfaces

# VIRUCIDAL  
BACTERICIDAL

(\*If this claim is made, organisms must be listed as follows:)

[REDACTED], Escherichia coli (E. coli), Staphylococcus aureus (Staph), Pseudomonas aeruginosa, Streptococcus pyogenes (Strep), Escherichia coli (E. coli) O157:H7,

(\*If this claim is made, organisms must be listed as follows:)

[REDACTED], Staphylococcus aureus (Staph), Klebsiella pneumoniae, Escherichia coli (E. coli) O157:H7, Camphylobacter jejuni, Listeria monocytogenes

### ACTIVE INGREDIENTS

Octyl decyl dimethyl ammonium chloride ..... 0.03990%  
Dioctyl dimethyl ammonium chloride ..... 0.01995%  
Didecyl dimethyl ammonium chloride ..... 0.01995%  
Alkyl (50% C<sub>14</sub>, 40% C<sub>12</sub>, 10% C<sub>16</sub>)  
dimethyl benzyl ammonium chloride ..... 0.05320%

INERT INGREDIENTS ..... 99.86700%  
Total ..... 100.00000%

KEEP OUT OF REACH OF CHILDREN

## CAUTION

See side (back) panels for additional precautionary statements.

EPA REG. NO. 1839-175  
EPA EST. NO. 1839-IL-01

STEPAN COMPANY  
22 West Frontage Road  
Northfield 60093

NET CONTENTS

ACCEPTED  
with COMMENTS  
in EPA Letter Dated  
NOV 22 2005  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 1839-175

4 7 6

(Institutional Label)

### DIRECTIONS FOR USE

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

Solvent Free Detergent Disinfectant Pump Spray is designed specifically as a general non-acid cleaner and disinfectant for use in (medical institutions) (hospitals) (nursing homes), homes, schools, hotels, and restaurants. It 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. The antibacterial formula cleans and disinfects in one step. May be used in the kitchen on counters, sinks, appliances, and stovetops. A rinse with potable water is required for surfaces in direct contact with food. In addition, this product deodorizes those areas which 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.

- (This product or product name) kills 99.9% of some bacteria\*. (Note: This statement requires disinfection use directions.)
- (This product or product name) kills 99.9% of bacteria\* in 5 minutes. (Note: This statement requires sanitization use directions.)
- (This product or product name) kills germs\*\* such as [REDACTED], Escherichia coli (E. coli), Staphylococcus aureus (Staph), Pseudomonas aeruginosa, Streptococcus pyogenes (Strep), Escherichia coli (E. coli) O157:H7, Influenza A<sub>2</sub> Hong Kong, Herpes Simplex Virus 2.

(For labels that list medical institutions, hospitals, nursing homes, and metal and/or stainless steel surfaces, the following statement must be used:)

(This product or product name) is not for use on critical or semi-critical medical devices.

**GENERAL CLEANING** – Spray soiled area then wipe with a dry paper towel or lint-free cloth. No rinsing necessary.

**DISINFECTION, DEODORIZING** - 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 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.

When using on food contact surfaces such as counters, stovetops, or appliances, thoroughly rinse all wetted and cleaned surfaces with potable (tap) water. This product should not be used to clean utensils, glassware, and dishes.

**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 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 10 minutes and flush.

**BACTERICIDAL ACTIVITY** - When used as directed, this product exhibits effective disinfectant activity against the organisms: [REDACTED], Escherichia coli (E. coli), Escherichia coli (E. coli) O157:H7, Staphylococcus aureus (Staph), Pseudomonas aeruginosa, Streptococcus pyogenes (Strep).

**\*\* VIRUCIDAL ACTIVITY** – When used as directed, this product exhibits effective virucidal activity against the organisms: Influenza A<sub>2</sub> Hong Kong, Herpes Simplex Virus 2.

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

**TO SANITIZE NON-FOOD CONTACT SURFACES and DEODORIZE:** Spray until thoroughly wet. Let stand 5 minutes. Then wipe. For heavily soiled areas a pre-cleaning step is required. This product is an effective sanitizer against Klebsiella pneumoniae, Staphylococcus aureus (Staph), Escherichia coli (E. coli) O157:H7, Campylobacter jejuni, Listeria monocytogenes.

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(Consumer Label)

Cleans streak-free and kills germs\*\* such as **[REDACTED]**, Escherichia coli (E. coli), Staphylococcus aureus (Staph), Pseudomonas aeruginosa, Streptococcus pyogenes (Strep), Escherichia coli (E. coli) O157:H7, Influenza A<sub>2</sub> Hong Kong, Herpes Simplex Virus 2. Cleans and disinfects most washable surfaces with no rinsing. The antibacterial formula cleans and disinfectants in one step. For use in the kitchen, bathroom, and other household areas. Effective on counter tops, sinks, appliances, cabinets, microwave ovens, floors, glazed ceramic tile, stainless steel, chrome, fiberglass, and glazed porcelain.

- This product kills 99.9% of some household bacteria\*. (Note: This statement requires disinfection use directions.)
- (This product kills 99.9% of bacteria\* in 5 minutes). (Note: This statement requires sanitization use directions.)

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

**General household cleaning:** Spray soiled area, then wipe with a dry paper towel or lint-free cloth. No rinsing is necessary.

**Disinfect/Deodorize:** Remove gross filth or heavy soil prior to application of the product. For hard non-porous surfaces such as counters and appliances, spray until thoroughly wet. Let stand for 10 minutes. A rinse is required for surfaces in direct contact with food.

**Bactericidal Activity** - When used as directed, this product exhibits effective disinfectant activity against the organisms: **[REDACTED]**, Escherichia coli (E. coli), Escherichia coli (E. coli) O157:H7, Staphylococcus aureus (Staph), Pseudomonas aeruginosa, Streptococcus pyogenes.

**\*\* Virucidal Activity** - When used as directed, this product exhibits effective virucidal activity against the organisms: Influenza A<sub>2</sub> Hong Kong, Herpes Simplex Virus 2.

**To Sanitize Non-Food Contact Surfaces and Deodorize:** Spray until thoroughly wet. Let stand 5 minutes. Then wipe. For heavily soiled areas a pre-cleaning step is required. This product is an effective sanitizer against Klebsiella pneumoniae, Staphylococcus aureus (Staph), Escherichia coli (E. coli) O157:H7, Camphylobacter jejuni, Listeria monocytogenes.

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(Consumer and Institutional)

## PRECAUTIONARY STATEMENTS

### Hazards to Humans and Domestic Animals

**CAUTION:** Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, 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 eyelids 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 the eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN/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.

### HOTLINE NUMBER (optional)

You may contact XXX/XXX-XXXX for emergency medical treatment information.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in an area inaccessible to children.

**CONTAINER DISPOSAL:** Do not reuse empty container. Rinse thoroughly before discarding in trash.