

1839-83

O 11/19/2007 C
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/8

NOV 19 2007

Mr. Thomas W. Isaac
Sr. Regulatory & Registration Specialist
Stephan Company
22 W. Frontage Rd.
Northfield, IL 60093

Subject: **Detergent Disinfectant Pump spray**
EPA Registration Number 1839-83
Application Dated July 19, 2007
Received Date July 19, 2007

Dear Mr. Isaac:

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

Proposed Amendment:

- Addition public health claim

1. The proposed label claims that the product, Detergent Disinfectant Pump Spray, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 3 minutes:

Staphylococcus aureus CA-MRSA (NRS 123)
Staphylococcus aureus CA-MRSA (NRS 384)
Paramyxovirus

Data provided supports these claims. The Agency has determined that "Community Associated" is acceptable label language for Methicillin Resistant *Staphylococcus aureus*. On the label, this claim must be stated as *Staphylococcus aureus* (CA-MRSA)(NRS 123) and (NRS 384).

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

2. The last-accepted label (and proposed label) claims that the product, Detergent Disinfectant Pump Spray, is an effective disinfectant against *Clostridium difficile* (vegetative form) on hard, non-porous surfaces. All references to *Clostridium difficile* must be removed from the product label. The Agency is no longer accepting claims for effectiveness against *Clostridium difficile* (vegetative cells).

Note: The Agency has re-evaluated its acceptance of the *Clostridium difficile* (vegetative form) on previously accepted claims and requests for new claims. Peer-reviewed scientific literature and case studies have consistently demonstrated that the *Clostridium difficile* spore is the source of public-health concern. In light of scientific guidance and supporting documentation, the Agency is certain that claims against the vegetative form of *Clostridium difficile* are true statements, but are used in such a way as to give a false or misleading impression to the purchaser (40 CFR 156.10(a)(5)(vii)). The Agency considers antimicrobial pesticides to be unique because of the critical nature of the threat to public health that may result from ineffective use of the products due to obsolete or misleading labeling. As a result, any reference to claims of effectiveness against *Clostridium difficile* (vegetative) OR *Clostridium difficile* (without having supporting data against *Clostridium difficile* spores) are unacceptable. To address the growing need for products in hospital/medical settings, the Agency is moving expeditiously to develop an appropriate test system and performance standards for *Clostridium difficile* spores.

3. ATCC designation numbers, or designation numbers, are required in one of the following locations:

- on the data matrix;
- on the master label (as optional text) with the listing of the organisms claimed; or
- as the final page of the master label (as optional text).

4. For claims against Avian Influenza A must include strain identification.

General Comments:

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy 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 Drusilla Copeland at (703) 308-6224 or Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: Efficacy Review dated 10/6/07

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
- For Use in Animal Housing Facilities (Poultry (Swine) Housing Facilities) (Public Restrooms) (as a Non-Acid Bowl (& Bathroom) Disinfectant Cleaner)

ACTIVE INGREDIENTS

n-Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈)
dimethyl benzyl ammonium chlorides..... 0.105%
n-Alkyl (68% C₁₂, 32% C₁₄) 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

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

NOV 19 2007
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-83

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 stovetops. 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 (and Poultry and Swine Premises):** (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.
- **Cooling Coils Disinfectant Cleaner.** (This product or product name) is a (ready-to-use) (non-abrasive) (one-step) disinfectant cleaner for (small air conditioner) (commercial air handling unit) (HVAC) cooling coils and (refrigeration equipment) (refrigerator) (freezer) evaporation coils. When using (this product or product name) to disinfect and clean (cooling coils) (evaporation coils), disconnect power to the unit before applying product. **Follow directions under the DISINFECTION, DEODORIZING AND CLEANING section.**

6/8

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: allow surface to remain wet for HIV-1 **1 minute** and for HBV and HCV **5 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: allow surface to remain wet for HIV-1 **1 minute** and for HBV and HCV **5 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: allow surface to remain wet for HIV-1 **1 minute** and for HBV and HCV **5 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: allow surface to remain wet for HIV-1 **1 minute** and for HBV and HCV **5 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 **3 minutes** (for Bovine Viral Diarrhea Virus (BVDV) **5 minutes**) (for Feline Calicivirus and Rabies virus **30 seconds**) (for Canine Parvovirus **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):

<i>Pseudomonas aeruginosa</i> , (ATCC 15442)	<i>Listeria monocytogenes</i> , (ATCC 35152)
<i>Staphylococcus aureus</i> , (ATCC 6538)	<i>Yersinia enterocolitica</i> , (ATCC 23715)
<i>Salmonella (choleraesuis) enterica</i> , (ATCC 10708)	<i>Enterococcus faecium</i> , (ATCC 6569)
<i>Escherichia coli</i> , (ATCC 11229)	<i>Corynebacterium ammoniagenes</i> , (ATCC 6871)
<i>Escherichia coli</i> O157:H7, (ATCC 43895)	<i>Salmonella (typhi) enterica</i> , (ATCC 6539)
<i>Streptococcus pyogenes</i> (Necrotizing Fasciitis-Group A) (V.A. Medical Center Isolate 04001)	

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 Isolate 99287)
Methicillin resistant Staphylococcus epidermidis (MRSE), (ATCC 51625)
Community Associated Methicillin Resistant Staphylococcus aureus (CA-MRSA), (NRS 123) Genotype USA400
Community Associated Methicillin Resistant Staphylococcus aureus (CA-MRSA), (NRS 384) Genotype USA300

(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 at 20 degrees Centigrade when the treated surface is allowed to remain wet for 5 minutes.

***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:

Canine Parvovirus
 Hepatitis A Virus (HAV)
 Poliovirus Type 1

This product or product name), when used on environmental, inanimate hard surfaces exhibits virucidal activity against: *Hepatitis B Virus* (HBV), *Hepatitis C Virus* (HCV) and *Bovine Viral Diarrhea Virus* (BVDV) when the treated surface is allowed to remain wet for 5 minutes; *Human Coronavirus*, *SARS associated Coronavirus* and *Avian Influenza A* for 2 minutes; *Paramyxovirus* (Mumps), *Rhinovirus type 39* (ATCC VR-340) and *Rotavirus* for 3 minutes; *HIV-1* (associated with AIDS) for 1 minute (60 seconds); and *Norovirus* (Norwalk virus), *Feline Calicivirus* and *Rabies Virus* for 30 seconds.

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

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 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 HBV and HCV 5 minutes, for HIV-1 1 minute. These contact times will not control other common types of viruses and bacteria.

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) (a cause of ringworm) (a cause of ringworm of the foot), 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 and before eating, drinking, chewing gum or using tobacco.

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.

(Note to reviewer: If the container size is one gallon or less, the following Storage and Disposal directions will be used:)

STORAGE AND DISPOSAL

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

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

(Note to reviewer: If the container size is greater than one gallon, the following Storage and Disposal directions will be used:)

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.

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.