

1839-83

11-7-2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

NOV - 7 2002

Subject: Detergent Disinfectant Pump Spray
EPA Registration No. 1839-83
Application Date: 5/01/02
Receipt Date: 5/14/02

Dear Mr. Isaac:

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

Addition of Hepatitis C Virus (HCV) claim to the label

GENERAL COMMENTS

Proposed label claims identifying the product, ONYX Detergent Disinfectant Pump Spray, as having virucidal activity against Hepatitis C Virus on hard, non-porous surfaces in the presence of organic soil (5% serum) are acceptable, as supported by MRID Nos. 456762-01 and -02 using Bovine Viral Diarrhea virus as a surrogate. Although the product demonstrated complete inactivation of the virus at all dilutions tested, a few minor modifications regarding specific procedural details must be submitted to the Agency:

- i. A more detailed description of the challenge BVDV strain, concerning the virus stock preparation and titration should be provided.
- ii. A full description of the host cell line (MDBK) including its preparation and susceptibility to BVDV should be provided. Are there other cell lines that are also susceptible to this virus and appropriate for use in the assay?
- iii. Please explain why only 0.5 ml of the virus-disinfectant mixture is neutralized when using column instead of the full 2.0 ml recovered from the plate.
- iv. A complete description of the infectivity assay using immunofluorescence should be provided.

CONCURRENCES

SYMBOL	11-510C						
SURNAME	11-510C						
DATE	11-05-02						

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. Please see the attached "Attachment" for corrections and revisions.

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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DETERGENT DISINFECTANT PUMP SPRAY

CLEANER	DEODORIZER
MILDEWSTAT (on hard	DISINFECTANT
inanimate surfaces)	TUBERCULOCIDAL
*VIRUCIDE	FUNGICIDE (against
	pathogenic fungi)

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 WARNING

See side 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

ACCEPTED
with COMMENTS
EPA Letter Dated:
NOV 7 2002
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
1839-83

NET CONTENTS

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

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DIRECTIONS FOR USE

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

Detergent Disinfectant Pump Spray is designed specifically as a general non-acid cleaner and disinfectant for use in homes, hospitals, nursing homes, schools, food processing plants, food service establishments, transportation terminals, office buildings, manufacturing facilities, lodging establishments, retail businesses 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 such as floors, walls, metal surfaces, stainless steel surfaces, porcelain, glazed ceramic tile, plastic 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 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 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.

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 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 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.

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 to penetrate and 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 to penetrate and 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.

TUBERCULOCIDAL ACTIVITY - This product exhibits disinfectant efficacy against *Mycobacterium tuberculosis* (BCG) in 10 minutes at 20 degrees Centigrade when used as directed on previously cleaned hard non-porous inanimate surfaces.

BACTERICIDAL ACTIVITY - When used as directed, this product exhibits effective disinfectant activity against the organisms: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Escherichia coli* 0157:H7, Methicillin resistant *Staphylococcus aureus* (MRSA), Vancomycin intermediate resistant *Staphylococcus aureus* (VISA), Vancomycin resistant *Enterococcus faecalis* (VRE) and meets the requirements for hospital use.

-VIRUCIDAL ACTIVITY - This product, when used on environmental, inanimate, non-porous surfaces, exhibits effective virucidal activity against HIV-1 (associated with AIDS), Canine Parvovirus, Poliovirus Type 1, Hepatitis B Virus (HBV) and Hepatitis C Virus (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 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.

Stepan Company
Northfield, IL 60093
EPA Reg. No. 1839-83

(Left Panel)

ACCEPTED
with COMMENTS
In EPA Letter Dated:
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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
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Amend 5/01/02

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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.

FUNGICIDAL ACTIVITY - This product is fungicidal against the pathogenic fungi, Trichophyton mentagrophytes (Athlete's Foot Fungus) when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, or other clean, non-porous, hard surfaces commonly contacted by bare feet.

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

KEEP OUT OF REACH OF CHILDREN. Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Avoid contamination of food. Remove contaminated clothing and wash before reuse. 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 on skin or clothing: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call 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.

ENVIRONMENTAL HAZARDS

(Required for products supplied in containers 5 gallons or greater.)

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.

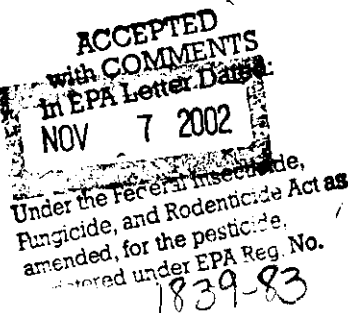
CONTAINER DISPOSAL - *Plastic Containers:* Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

For containers 1 gallon or less: Do not reuse empty container (bottle, can, bucket). Wrap container and put in trash.

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.

Stepan Company
Northfield, IL 60093
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(Right Panel)



Amend 5/10/02