

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 23 2004

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

Subject: Veterinarian Type Disinfectant
EPA Registration No. 1839-100
Application Date: 6/25/04
Receipt Date: 6/28/04

Dear Mr. Isaac:

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

- . Addition of non-public health viruses
- . Addition of a Disinfection/Virucide Dilution chart
- . Addition of a Virucidal Dilution chart
- . Expanded marketing claims and environmental surfaces
- . Specific use directions for application areas

LABEL COMMENTS

1. You must delete the organism "Feline Calicivirus" from the label because it may be a surrogate for Norwalk virus. If you want this on your label, you must submit efficacy data to support it.

GENERAL COMMENTS

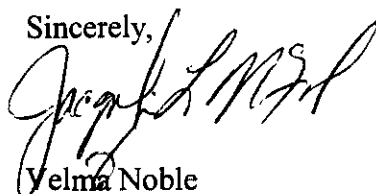
A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

CONCURRENCES

SYMBOL	1839-100						
SURNAME	T. Isaac						
DATE	09-23-04						

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

Sincerely,



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

Veterinarian Type Disinfectant

- DISINFECTANT
- DETERGENT
- DEODORANT
- *VIRUCIDE
- MILDEWSTAT
- With Organic Soil Tolerance for Veterinary Clinics, Animal Hospitals, Pet Shops, Kennels, Animal Care Facilities, Tack Shops, Animal Life Science Laboratories, Breeding and Grooming Establishments and Farms

ACTIVE INGREDIENTS

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides.....	4.5%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides.....	4.5%
INERT INGREDIENTS	<u>91.0%</u>
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

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.

See side (back) panel for additional precautionary statements.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
SEP 23 2004

EPA REG. NO. 1839-100
 EPA EST. NO. 1839-IL-01

STEPAN COMPANY
 22 West Frontage Road
 Northfield, IL 60093

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 1839-100

NET CONTENTS

This product (product name) contains no phosphorous.

By effectively controlling odors, this product (product name) minimizes labor.

When used as directed, this product (product name) will deodorizes surfaces where bacterial growth can cause malodors.

Cross contamination is of major housekeeping concern. This product (product name) has been formulated to aid in the reduction of cross-contamination on treated surfaces.

This product (product name) delivers non-acid toilet and urinal disinfection performance in an economical concentrate.

This product (product name) is a concentrated disinfectant that is effective against a broad spectrum of bacteria and is *virucidal when used as directed.

This product (product name) is an economical concentrate that can be used with a mop and bucket, trigger sprayers and cloth/sponge.

This product (product name) will not leave a grit or soap scum.

This product (product name) is a versatile disinfectant and *virucide for use in Veterinarian, Animal Care and Farm premises and equipment.

This product (product name) inhibits odor causing bacterial growth on moist surfaces and deodorizes by killing microorganisms that cause offensive odors.

This product (product name) neutralizes musty odors and tough odors from pet accidents on contact.

Use this product (product name) on multi-touch surfaces responsible for cross-contamination.

This product (product name) provides long lasting freshness against tough (pet) odors such as odors from litter boxes and pet accidents.

This product (product name) for use in:

- Veterinary clinics, animal hospitals, animal life science laboratories, kennels, pet animal kennels, breeding and grooming establishments, pet animal quarters, zoos, pet shops, tack shops and other animal care facilities.
- Animal holding areas, veterinary waiting rooms, veterinary examination rooms, veterinary X-ray rooms, veterinary operating rooms.
- Animal transportation vehicles.

This product (product name) may be used on washable hard non-porous surfaces:

- Non-food contact glass, metal, stainless steel, glazed porcelain, glazed ceramic, granite, marble, plastic, chrome and vinyl.
- Toilet bowls, urinals, sinks, faucets.
- Enameled surfaces, painted woodwork, Formica[®], non-porous vinyl and plastic upholstery.
- Tables, chairs, desks, lifts, washable walls, cabinets, doorknobs and garbage cans.
- Veterinarian examination tables, Veterinarian X-ray tables, animal washing areas, animal grooming areas.
- Telephone receivers, telephone keypads, telephones.
- Kennels, kennel runs, cages, floors, conductive flooring.
- Animal feeding and watering equipment.

This product (product name) is recommended for Poultry Premise Sanitation (Hatcheries):

Egg Receiving Area	Tray Dumping Area	Chick Processing Area
Egg Holding Area	Chick Holding Area	Chick Loading Area
Setter Room	Hatchery Room	Poultry Buildings

This product (product name) is recommended for Swine Premise Sanitation:

Farrowing Barns and Areas	Dressing Plants	Blocks
Waterers and Feeders	Loading Equipment	Creep Area
Hauling Equipment	Nursery	Chutes

Veterinarian Type Disinfectant (this product) (product name) is designed for use in veterinary clinics, animal hospitals, animal laboratories, animal life science laboratories, animal care facilities, kennels, tack shops, pet shops, zoos, pet animal quarters, stables, farms and pet grooming/breeding establishments. When used as directed, this formulation is specifically designed to disinfect, deodorize and clean inanimate, hard, non-porous surfaces: walls, floors, sink tops, furniture, operating tables, kennel runs, cages, and feeding and watering equipment. In addition, this product will deodorize those areas that are generally hard to keep fresh smelling such as garbage storage areas, empty garbage bins and cans, and any other areas which are prone to odors caused by microorganisms.

DIRECTIONS FOR USE

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

DISINFECTION - For disinfecting, add 1 ounce of this product (product name) to one gallon of water. Apply this solution with a mop, cloth, sponge, hand pump trigger sprayer, or low coarse pressure sprayer so as to wet all surfaces thoroughly. Allow surfaces to remain wet for 10 minutes and then let air dry.

BACTERICIDAL ACTIVITY - When used as directed, this product (product name) demonstrates effective disinfectant activity against *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schottmuelleri*, *Salmonella choleraesuis*, *Streptococcus faecalis*, *Shigella dysenteriae*, *Enterobacter aerogenes* and *Staphylococcus aureus*. When used as directed, this formulation is an effective disinfectant against *Pseudomonas aeruginosa* in animal hospitals and laboratories.

***VIRUCIDAL ACTIVITY** - When used at the 1 ounce to one gallon or equivalent dilution rate (703 ppm (mg/L)) active quat), this product exhibits effective virucidal activity on inanimate, hard surfaces against Canine Distemper, Pseudorabies virus, Vaccinia virus, Influenza A2, Herpes Simplex, Adenovirus Type 2, and Bovine Viral Diarrhea Virus (BVDV).

Disinfection and Virucidal (1 oz. per gallon) Dilution Chart

Ounces of Product	Water
¼ oz.	Quart
½ oz.	½ gallon
1 oz.	Gallon
2 ozs.	2 gallons
5 ozs.	5 gallons
15 ozs.	15 gallons
30 ozs.	30 gallons

At 4 ounces per gallon or equivalent dilution rate (2812 ppm (mg/L) active quat), this product (product name) is effective against the following viruses on hard non-porous environmental surfaces:

- | | | |
|-------------------------|-----------------------------------|-------------------------------|
| Canine Parvovirus (CPV) | Canine Parainfluenza Virus | Feline Infectious Peritonitis |
| Canine Adenovirus | Feline Calicivirus | Feline Rhinotracheitis |
| Canine Coronavirus | Infectious Canine Hepatitis Virus | |

Canine Parvovirus (CPV) Activity: At 4 ounces per gallon of water or equivalent dilution, this product (product name) inactivates Canine Parvovirus (CPV) on hard, non-porous, environmental surfaces in the presence of 5% blood serum with a 10 minute contact time.

Virucidal (4 ozs. per gallon) Dilution Chart

Ounces of Product	Water
1 oz.	quart
2 ozs.	½ gallon
4 ozs.	gallon
8 ozs.	2 gallons
20 ozs.	5 gallons
60 ozs.	15 gallons
120 ozs.	30 gallons

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

MILDEWSTAT - To control mold and mildew on pre-cleaned hard, non-porous surfaces, add 1 ounce to one gallon or equivalent dilution of water. Apply use-solution with a cloth, mop, sponge, hand pump trigger sprayer or low pressure coarse sprayer making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth reappears.

DEODORIZATION - To deodorize, add 1 ounce of this product (product name) per gallon of water or equivalent dilution of water (703 ppm (mg/L) active quat). Excess material should be wiped up or allowed to air dry.

For (pet) (domestic animal) odors: Use on carpets, floors, walls, tile, cages, pet beds, litter boxes, mats, floor coverings, area rugs or any surface soiled by a pet (domestic animal). Test a small inconspicuous area first. Blot problem area, then follow directions for DEODORIZATION.

For cleaning and disinfecting the following hard non-porous surfaces: equipment, utensils, instruments, cages, kennels, stables, stalls, and catteries. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use solution of 1 ounce per gallon (703 ppm active quat) of water (or equivalent dilution) for a period of 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers and other equipment which dispenses food or water with soap or detergent and rinse with potable water before reuse.

For feeding and watering equipment, RINSE WITH POTABLE WATER after disinfecting.

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

POULTRY (AND SWINE) PREMISE SANITATION DIRECTIONS-

Site Preparation: The first step in any on-going sanitation program should be the removal of gross contamination and debris. This may be accomplished using a shovel, broom, or vacuum depending on the area to be disinfected. The efficacy of even the most efficient germicidal cleaner is reduced in the presence of heavy organic matter. Once the heavy debris is eliminated thoroughly clean all surfaces with soap or detergent and rinse with water.

Cleaning And Disinfection: For all general cleaning and disinfecting use 4 ounces of this product (product name) per gallon of water. Apply this product (product name) using a cloth, mop, hand pump trigger sprayer or low pressure coarse sprayer so as to thoroughly wet surface to be disinfected. Allow to remain wet for 10 minutes and then let air dry. For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution after each use.

DISINFECTION/VIRUCIDAL ACTIVITY OF POULTRY/TURKEY EQUIPMENT, SWINE QUARTERS, ANIMAL QUARTERS AND KENNELS DIRECTIONS -

Remove all animals and feeds from premises, trucks, cars, coops and crates. Remove all litter, droppings and manure 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. Use 4 ounces of this product (product name) per gallon of water. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes. Ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

Hatcheries: Use 4 ounces of this product (product name) per gallon of water to treat the following hard non-porous surfaces: hatching, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more. Rinse with potable water before reuse. Then allow to air dry.

Vehicles: Clean all vehicles including mats crates, cabs, and wheels with high pressure water and this product (product name). Use 4 ounces per gallon to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more.

RENDERING PLANT/DRESSING PLANT DISINFECTION DIRECTIONS - Disinfect equipment, utensils, walls and floors in poultry and dressing plants with a use-solution of 1 ounce of this product (product name) per gallon of water or equivalent use dilution (703 ppm (mg/L) active quat). Equipment and utensils must remain wet for 10 minutes then thoroughly rinsed with potable water before operations are resumed. Disinfect all rooms, exterior walls and loading platforms of dressing plants.

VETERINARY PRACTICE/ANIMAL CARE/ANIMAL LABORATORY/ZOOS/PET SHOP/KENNELS/ BREEDING AND GROOMING ESTABLISHMENTS/TACK SHOPS/ANIMAL LIFE SCIENCE LABORATORIES DISINFECTION & VIRUCIDAL ACTIVITY DIRECTIONS -

For cleaning and disinfecting the following hard non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feed from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 4 ounces of this product (product name) per gallon of water (or equivalent dilution) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers and other equipment that dispenses food or water with soap or detergent, and rinse with potable water before reuse.

FARM PREMISE DISINFECTION DIRECTIONS (For Use in Equine, Dairy and Hog Farms):

Do not use in milking stalls, milking parlors or milk houses.

1. Remove all animals and feed from premises, vehicles and enclosures.
2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate all surfaces with a use solution of 4 ounces of this product (product name) per gallon of water (or equivalent dilution) for a period of 10 minutes.
6. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used in removing litter and manure.
7. Ventilate buildings, cars, trucks, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried.
8. Thoroughly scrub all treated feed racks, managers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

NON-ACID TOILET BOWL DISINFECTANT DIRECTIONS - Remove gross filth prior to disinfecting.

From Concentrate: Add 1 ounce of this product (product name) to the toilet bowl water or urinal and mix. Brush thoroughly over exposed surfaces and under the rim with toilet bowl brush. Allow to stand for 10 minutes and flush.

From Use-solution: Empty toilet bowl or urinal and apply 1 ounce of this product (product name) per gallon of water or equivalent dilution to exposed surfaces including under the rim with a toilet bowl brush, a cloth, mop, sponge, hand pump trigger sprayer, or low pressure sprayer; brush or swab thoroughly and allow to stand for 10 minutes and flush. For sprayer application use a coarse spray device.

(Alternative language for bag in the box dispensing equipment)

DIRECTIONS FOR BAG-IN BOX CONTAINERS

How to use this package: This package is designed to be used with dilution control systems only. Open package and connect to dispenser according to the directions on the box.

Trigger sprayers: Fill bottle from dispenser. Apply to surfaces according to directions above.

Mop Buckets: Fill bucket from dispenser. Set up "Wet Floor" signs. Mop floor surfaces as specified in directions above.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER

KEEP OUT OF REACH OF CHILDREN. CORROSIVE. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. May be fatal if absorbed through skin. Harmful if swallowed. Wear goggles or face shield, rubber gloves, and protective clothing. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

(The following statement is required for product supplied in 5 gallon containers or greater.)

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic invertebrates. 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 - Do not reuse empty container. Triple rinse empty container with water. Return metal drum then offer for reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers may be disposed of in a sanitary landfill, incinerated, or if allowed by local authorities, by burning. If burned, stay out of smoke.

For containers 1 gallon or less: Do not reuse empty container. Wrap in newspaper 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.