

JUN 26 2003

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

Subject: NP 12.5 Detergent/Disinfectant  
EPA Registration No. 1839-80  
Application Date: 3/27/03  
Receipt Date: 3/28/03

Dear Mr. Isaac:

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

- . Update First Aid Statements
- . Update Precautionary Statements
- . Addition of expanded, specific environmental surfaces
- . Addition of Terminal Sterilant Statement
- . Addition of U.S. Public Health Service -Food Service Sanitization Recommendations
- . Addition of Wisconsin State Division of Health
- . Revised Fungicidal Activity section

### GENERAL COMMENTS

Under the "U.S. Public Health Service - Food Service Sanitization Recommendations" add the following sentence: "Allow sanitized surfaces to drain and air dry. Do not rinse."

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	175100						
SURNAME	15-10-03						
DATE	16-11-03						

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

Sincerely,

A handwritten signature in black ink, appearing to read "Velma Noble", written in a cursive style.

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

376

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JUN 26 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 1839-80

**NP 12.5**

## Detergent/Disinfectant

CLEANER  
DETERGENT  
SANITIZER

FUNGICIDE (against pathogenic fungi)  
MILDEWSTAT (on hard inanimate surfaces)

DISINFECTANT  
DEODORIZER  
\* VIRUCIDE

### 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..... 6.25%  
n-Alkyl (68% C<sub>12</sub>, 32% C<sub>14</sub>) dimethyl  
ethylbenzyl ammonium chlorides ..... 6.25%

**INERT INGREDIENTS** ..... 87.50%  
Total..... 100.00%

EPA REG. NO. 1839-80  
EPA EST. NO. 1839-IL-01

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**

See side panels for additional precautionary statements.

STEPAN COMPANY  
22 West Frontage Road • Northfield, IL 60093

NET CONTENTS

(Center panel)

America 03/27/03

## DIRECTIONS FOR USE

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

NP 12.5 Detergent/Disinfectant is designed to provide effective cleaning, deodorization, sanitization and disinfection specifically for hospitals, nursing homes, schools, food processing plants, food service establishments where housekeeping is of prime importance in controlling the hazard of cross contamination.

This product, when used as directed, is formulated to disinfect hard, non-porous, inanimate, environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, toilet bowls, sink tops, cabinets, tables, chairs and telephones. For larger areas: operating rooms, patient care facilities and restrooms, this product is designed to provide both general cleaning and disinfecting.

This product deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls, and other areas which are prone to odors caused by microorganisms.

This product sanitizes previously cleaned and rinsed non-porous food contact surfaces: tanks, chopping blocks, counter tops, drinking glasses, and eating utensils.

*(For labels that list medical premises and/or stainless steel surfaces, one of the following statements must be used:)*

This product is not 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 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 medical device surfaces.

**DISINFECTION** - To disinfect inanimate, hard surfaces, add 0.5 ounce of this product per gallon of water. Apply solution with a mop, cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid. Remove gross filth or heavy soil prior to application of this product. Prepare a fresh solution for each use.

**To disinfect toilet bowls**, flush toilet, add 0.5 ounce of this product directly to the bowl water. Swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush.

**BACTERICIDAL ACTIVITY** - When diluted at the rate of 0.5 ounce per gallon of water, this product exhibits effective disinfectant activity against the organisms: *Pseudomonas aeruginosa* PRD 10, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schottmuelleri*, *Salmonella choleraesuis*, *Streptococcus salivarius*, *Brevibacterium ammoniagenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, *Enterobacter aerogenes*, and *Staphylococcus aureus* and meets all requirements for hospital disinfectants.

**MILDEWSTAT** - To control mold and mildew on pre-cleaned, hard, non-porous surfaces add 0.5 ounce of this product per gallon of water. Apply solution with a cloth, mop or sponge 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 appears.

**FUNGICIDAL ACTIVITY** - At the 0.5 ounce per gallon dilution, this product is also 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, exercise facilities or other clean, hard, non-porous, surfaces commonly contacted by bare feet.

**\* VIRUCIDAL ACTIVITY** - This product when used on environmental, inanimate hard surfaces at 0.5 ounce per gallon of water exhibits effective virucidal activity against Influenza A2/Japan (representative of the common flu virus), Herpes Simplex Type 1 (causative agent of fever blisters), Adenovirus Type 5 (causative agent of upper respiratory infections), Vaccinia virus (representative of the pox virus group), and Human Immunodeficiency Virus (HIV-1).

**KILLS HIV-1 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.)

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF 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.

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

**SANITIZATION** - To sanitize previously cleaned and rinsed non-porous food contact surfaces prepare a 200 ppm active quaternary solution by adding 1 ounce of this product to 5 gallons of water.

To sanitize immobile items such as tanks, chopping blocks, and counter tops, flood the area with a cloth or sponge making sure to wet all surfaces completely for at least 60 seconds. Let air dry. Prepare a fresh solution for each use.

To sanitize mobile items such as drinking glasses and eating utensils, immerse in a 200 ppm active quaternary solution for at least 60 seconds making sure to immerse completely. Remove and let air dry. Prepare a fresh solution daily or more frequently as soil is apparent.

When used for sanitization of previously cleaned food equipment or food contact items, limit active quaternaries to 200 ppm. At this level NO POTABLE WATER RINSE IS REQUIRED. This product is an effective sanitizer when diluted in water up to 600 ppm hardness ( $\text{CaCO}_3$ ).

**DIRECTIONS FOR SANITIZING FOOD PROCESSING EQUIPMENT, UTENSILS, AND FOOD CONTACT ARTICLES REGULATED BY 21CFR sec 178.1010: b(22), c(17).**

1. Scrape, flush or pre-soak articles (whether mobile or stationary) to remove gross food particles and soil.
2. Thoroughly wash articles with an appropriate detergent or cleaner.
3. Rinse articles thoroughly with potable water.
4. Sanitize articles using a solution of 1 ounce of this product 5 per gallons of water (200 ppm active quaternary). Articles that can be immersed in solution should remain in solution for 60 seconds. Articles too large for immersion should be thoroughly wetted by rinsing, spraying or swabbing.
5. Remove immersed items from solution to drain and then air dry. Non-immersed items should also be allowed to air dry.

**U.S. PUBLIC HEALTH SERVICE - FOOD SERVICE SANITIZATION RECOMMENDATIONS**

**CLEANING AND SANITIZING:** Equipment and utensils shall be thoroughly pre-flushed or pre-scraped, and when necessary, pre-soaked to remove gross food particles and soil.

1. Thoroughly wash equipment and utensils in a hot detergent solution. Rinse utensils and equipment thoroughly with potable water.
2. Sanitize equipment and utensils by immersing in 1 ounce of this product per 5 gallons of water (200 ppm active quaternary) for at least 60 seconds at a temperature of 75°F. This dilution is equivalent to a solution containing 50 ppm available chlorine.
3. For equipment and utensils too large to sanitize by immersion, apply 1 ounce of this product per 5 gallons of water (200 ppm active quaternary) by rinsing, spraying or swabbing. Allow the items to remain thoroughly wet for at least 60 seconds, then let air dry.

*(This statement is required for marketing food contact sanitizers in Wisconsin.)*

**WISCONSIN STATE DIVISION OF HEALTH - DIRECTIONS FOR EATING ESTABLISHMENTS:**

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleanser.
3. Rinse with potable water.
4. Sanitize in a solution of 1 ounce per 5 gallons of this product (200 ppm active quaternary). Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board to air dry.
6. Fresh sanitizing solution should be prepared at least daily or when visibly soiled or diluted.

**NOTE:** A clean potable water rinse following sanitization is not permitted under Section HSS 196.33 of the Wisconsin Administrative Code.

*(Alternative language for clean in place, closed loop dilution centers.)*

**WISCONSIN STATE DIVISION OF HEALTH - DIRECTIONS FOR EATING ESTABLISHMENTS**

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with potable water.
4. Sanitize in a solution from the Closed Loop Dilution Center (200 ppm active quaternary). Immerse all utensils at least two minutes or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board to air dry.
6. Fresh sanitizing solution should be prepared at least daily or when visibly soiled or diluted.

**NOTE:** A clean potable water rinse following sanitization is not permitted under Section HSS 196.33 of the Wisconsin Administrative Code.

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER. KEEP OUT OF REACH OF CHILDREN. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if absorbed through skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, rubber gloves, and protective clothing. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking 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 on skin or clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

**If swallowed:** Call 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.

*(Note: If container size is 5 gallons or greater, the following Environmental Hazards statement must be used.)*

### ENVIRONMENTAL HAZARDS

This product 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** - 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 (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.