

1839-144

08/13/2003
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

116

AUG 13 2003

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

Subject: NP 5.5 (D & F) Detergent/Disinfectant
EPA Registration No. 1839-144
Amendment dated: May 14, 2003
EPA Received date: May 15, 2003

Dear: Mr. Thomas W. Isaac,

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

Proposed Amendment

- Update the First Aid Statement consistent with PR Notice 2001-1
- Update Precautionary Statements consistent with the Label Review Manual
- Addition of Environmental Hazards Statement
- Addition of optional 1 line statement **TERMINAL STERILANT STATEMENT**
- Replace "mechanical sprayer" mode of delivery with "hand pump trigger sprayer" and "low pressure coarse spray".

Conditions

- Revise the label as follows:
 1. Qualify the phrase hard surfaces as hard *non-porous* surfaces in the Disinfection Directions and Fungicidal Activity.

CONCURRENCES							
SYMBOL	7510(c)						
IRNAME	A Peters						
ITE	8/13/03						

2. In the General cleaning directions the last phrase should read

.....or lint-free cloth

3. Revise the Precautionary Language as follows:

Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles or face shield, or safety glasses) rubber gloves and *protective clothing* when handling.....

General Comments

A stamped label is enclosed for your records. Please submit three copies (3) copies of your final printed label before distributing or selling the product bearing the revised labeling. If the above conditions are not compiled with, the registration will be subject to cancellation in accordance with FIFRA section (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of the condition. Should you have any questions concerning this letter please contact me at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Divisions (7510c)

NP 5.5 HW (D&F)

Detergent/Disinfectant

CLEANER
DETERGENT
DEODORIZER

DISINFECTANT
*VIRUCIDE

FUNGICIDE (against pathogenic fungi)
SANITIZER (non-food contact surfaces)
MILDEWSTAT (on hard, inanimate surfaces)

ACTIVE INGREDIENTS

Octyl decyl dimethyl ammonium chloride	1.650%
Dioctyl dimethyl ammonium chloride	0.825%
Didecyl dimethyl ammonium chloride	0.825%
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chlorides	2.200%
INERT INGREDIENTS	94.500%
TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panel for additional precautionary statements.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 13 2003
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-144

EPA REG. No. 1839-144
EPA EST. No. 1839-IL-01

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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.

NP 5.5 HW (D&F) Detergent/Disinfectant is a phosphate-free formulation designed to provide effective cleaning, deodorizing, non-food contact sanitizing, and disinfection specifically for hospitals, nursing homes, schools, food processing plants, food service establishments, transportation terminals, office buildings, manufacturing facilities, lodging establishments, retail businesses and athletic/recreational facilities where housekeeping is of prime importance in controlling the hazard of cross contamination.

This product, when used as directed, is formulated to sanitize and disinfect the following hard non-porous inanimate environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, and cabinets. For larger areas, such as operating rooms and patient care facilities, this product is designed to provide both general cleaning, disinfecting, and sanitizing of non-food contact surfaces.

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.

(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 medical device surfaces.

GENERAL CLEANING & DEODORIZATION – Apply product to soiled area with a mop, cloth sponge, or hand pump trigger sprayer. Product can be diluted at 1¼ ounces per gallon or applied at full strength. Thoroughly wet soiled surface and scrub as necessary. Rinse surface with potable water and wipe dry with a dry paper towel or line-free cloth.

DISINFECTION - To disinfect inanimate, hard surfaces, apply solution with a mop, cloth, sponge, hand pump trigger sprayer, or low pressure coarse sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid. For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

GENERAL DISINFECTION - Add 1¼ ounces of this product per gallon of water.

HOSPITAL DISINFECTION - Add 2 ounces of this product per gallon of water.

To disinfect toilet bowls: Remove gross filth prior to disinfection, flush toilet, add 1¼ ounces 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 10 minutes and flush.

To disinfect food processing premises: floors, walls, storage areas and equipment, add 1¼ ounces 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. Before using this product, food products and packaging materials must be removed from the area or carefully protected. After use, all surfaces in the area must be thoroughly rinsed with potable water.

To disinfect food service food contact surfaces: countertops, appliances, tables, add 1¼ ounces of this product per gallon of water. Apply solution with a cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow the surface to remain wet for 10 minutes, then remove excess liquid and rinse the surface with potable water. This product cannot be used to clean the following food contact surfaces: utensils, glassware and dishes.

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SANITIZATION OF NON-FOOD CONTACT SURFACES - To sanitize porous and non-porous environmental surfaces such as floors, walls, tables, add 1 ounce of this product per 2¾ gallons of water. Apply solution with a mop, cloth, sponge, hand pump trigger sprayer, or low pressure coarse sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 60 seconds, then remove excess liquid. For heavily soiled areas, a pre-cleaning step required. Prepare a fresh solution for each use. This product is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae*.

BACTERICIDAL ACTIVITY - When diluted at the rate of 2 ounces per gallon of water, this product exhibits effective disinfectant activity against the organisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Streptococcus pyogenes*, *Enterobacter aerogenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, *Brevibacterium ammoniagenes*, *Salmonella typhi*, and *Serratia marcescens*.

When diluted at the rate of 2 ounces per gallon of water, this product exhibits effective disinfectant activity against *Pseudomonas aeruginosa* in addition to the above microorganisms and meets all requirements for hospital use.

*** VIRUCIDAL ACTIVITY** - This product when used on environmental, non-porous, inanimate, hard surfaces at 2 ounces per gallon of water exhibits effective virucidal activity against Influenza A/Brazil (lower respiratory tract disease) and Human Immunodeficiency Virus Type 1 (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.

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard, non-porous surfaces add 1¼ ounces 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 2 ounces per gallon dilution, this product is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* (Athlete's Foot Fungus), when used on hard surfaces in such areas as locker rooms, dressing rooms, shower and bath areas, and in exercise facilities. Allow the surface to remain wet for 10 minutes, then remove excess liquid. Diluted product should be applied daily or more frequently with heavy facility use.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE IN WATER UP TO 400 PPM HARDNESS (AS CaCO₃) IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

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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. Wear goggles or face shield and rubber gloves when handling. May be fatal if absorbed through skin. Harmful if swallowed. Remove contaminated clothing and wash 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 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 product supplied in containers 5 gallons 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 (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.

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