

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV - 5 2002

Michael G. Sarli  
Regulatory Specialist  
Steris  
P.O. Box 147  
St. Louis , Mo 63166-0147

Subject: Process NPD  
EPA Registration No. 1043-90  
Amendment dated: August 5, 2002  
EPA Received date: August 7, 2002

Dear: Mr. Michael G. Sarli,

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

**Proposed Amendment**

- Response to Agency letter dated June 16, 2002

**Label Comment:**

1. Under "Method and Rate of Application" include the statement "Clothing should either be rinsed or laundered before reuse"

**General Comments**

A stamped label is enclosed for your records. Please submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions regarding this letter, please contact Velma Noble at

(703) 308-6233

**CONCURRENCES**

SYMBOL							
SURNAME							
DATE							

Sincerely,

A handwritten signature in black ink, appearing to read "Velma Noble". The signature is written in a cursive style with a large initial "V".

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

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS DANGER Corrosive Causes irreversible eye damage and skin burns. May be fatal if absorbed through the skin. Harmful if swallowed or inhaled. Do not get in eyes, on skin, or on clothing. Wear safety goggles, protective clothing, and rubber gloves. Do not breathe vapor or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse. ENVIRONMENTAL HAZARD STATEMENT (For use on containers 5 gallons and larger) 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.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. CLEANING AND DISINFECTING: Add one-half ounce (15cc) to each measured gallon of water used. Always add this product to pre-measured water. Gently mix for a uniform solution. Apply solution with a cloth, sponge, mop, brush or course spray using normal cleaning methods. Thoroughly wet all surfaces to be cleaned. Allow treated surfaces to soak for 10 minutes. Then remove excess solution with a wring-out applicator. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution when it becomes dirty and replace with a fresh solution. This is a complete product. Do not add other chemicals. Use only as directed.

ANIMAL HUSBANDRY, ANIMAL RESEARCH, POULTRY FACILITY CLEANING AND DISINFECTING: Remove or cover all food, feedstuffs, packaging materials and livestock. Remove all litter, manure and other debris from floors and walls, scrape if necessary. Empty all troughs, racks, feeders and waterers. Saturate all surfaces with a 1:256 solution (one-half ounce per gallon prepared as directed above). Scrub to loosen adhering soils. Allow to soak for 10 minutes, then pick up excess with a wring-out applicator. Flush feeders and waterers with potable water after disinfecting. Drain all surfaces, ventilate buildings and allow to air dry before use or rehousing animals.

CLEANING AND DISINFECTING FOOD PREPARATION AND PROCESSING FACILITIES AND EQUIPMENT: Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the use-solution (one-half ounce per gallon prepared as directed above). Scrub to loosen all soils. Allow to soak for 10 minutes. Thoroughly rinse all wetted and cleaned surfaces with potable water.

VIRUCIDAL ACTIVITY AGAINST CANINE PARVOVIRUS, FELINE CALCIVIRUS AND INFECTIOUS BURSAL DISEASE: Dilute product 1:64 (2 oz. per gallon) and apply as directed above.

FOGGING AS AN ADJUNCT TO REGULAR CLEANING AND DISINFECTING: This product may be used in fogging (wet misting) as an adjunct either preceding or following regular cleaning and disinfecting procedures to sanitize surfaces in research and manufacturing facilities, in poultry operations, hatcheries, swine operations, animal care facilities, animal research facilities, livestock operations, veterinary facilities, zoos and kennels. Use a 1:256 dilution (one-half ounce per gallon of water). Remove all animals and feed from areas to be fogged. Remove all litter and manure from surfaces or areas traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces. Fog the desired area at 32 to 64 ounces of use dilution per 1000 cubic feet using equipment with an automatic timer. Do not remain in treated areas; allow at least two hours after fogging is complete before reentering fogged area. Before fogging remove or cover any food or packaging material with waterproof coverings. Treated surfaces must be thoroughly scrubbed with Process NPD at a 1:256 dilution and rinsed with potable water before reuse. Do not rehouse livestock or employ equipment until treatment has dried.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in healthcare settings 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 HIV-1 (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS: Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of a 1:256 use-solution (one-half ounce per gallon). Prepare and apply solution as directed in paragraphs above. Contact Time: While the HIV-1 virus is inactivated in 30 seconds, use a 10-minute contact time for disinfection of all organisms on this label.

Infectious Materials Disposal: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Pesticide Storage: Store in a secure area away from flammable materials. If frozen, thaw and re-mix before use.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and Local authorities, by burning. If burned, stay out of smoke.

Process NPD One Step Germicidal Detergent

Germicide Virucide\* Detergent Deodorizer Concentrate

EPA REG. NO. 1043-90 EPA Est. No. 1043-MO-1

FOR AGRICULTURAL, INDUSTRIAL AND INSTITUTIONAL USE ONLY

ACCEPTED with COMMENTS In EPA Letter Dated: NOV 5 2002 Active Ingredients: Octyl decyl dimethyl ammonium chloride 4.60% Diocetyl dimethyl ammonium chloride 2.30% Didecyl dimethyl ammonium chloride 2.30% Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride 6.44% Inert Ingredients 84.36% Fungicide, and Deodorizer registered under EPA Reg. No. 1043-90 KEEP OUT OF REACH OF CHILDREN DANGER FIRST AID

Have the product container or label with you when calling poison control center or doctor or going for treatment. If In Eyes: Hold eye open and rinse slowly and gently with water for 10-15 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye. 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 immediately for treatment advice. If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a 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 immediately for treatment advice. NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

NET CONTENTS:

STERIS Corporation 7501 Page Avenue St. Louis, MO 63133 U.S.A.

PRODUCT MADE IN THE U.S.A.

This product is a research-developed hard water effective, phosphate-free concentrated germicidal detergent system designed to simultaneously clean, disinfect and deodorize in the presence of 5% organic soil (serum) when diluted with 400 ppm hard water. It is intended for use on washable hard, non-porous environmental surfaces such as floors, walls, counters, tools, carts, and other equipment in pharmaceutical and cosmetic facilities, and in food processing, preparation and service facilities, in animal husbandry, poultry and feed processing facilities, veterinary clinics, animal research facilities and in other indoor areas where infectious contamination control is a necessity.

Use the use-solution for the cleaning and disinfection of metal surfaces such as stainless or galvanized steel and chrome, porcelain, plastics, glass, tile, washable painted or varnished surfaces, concrete, as well as resilient vinyl, asphalt, linoleum, rubber, terrazzo or other combination-type floors.

GERMICIDE: Passes A.O.A.C. Germicidal Use-Dilution Method (S. aureus, S. choleraesuis) when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

It has also been shown in the A.O.A.C. Use-Dilution Test, when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per gallon) in the presence of 5% organic soil (serum), 10 minutes at 20°C to inactivate:

- Acinetobacter calcoaceticus, ATCC 19606 Pseudomonas aeruginosa, ATCC 9027 Bordetella avium, ATCC 35086 Pseudomonas cepacia, ATCC 25609 Bordetella bronchiseptica, ATCC 10580 Salmonella enteritidis, ATCC 13076 Campylobacter jejuni, ATCC 29428 Salmonella typhimurium, ATCC 14028 Candida albicans, Clinical Isolate Serratia marcescens, ATCC 8100 Candida parapsilosis, Clinical Isolate Shigella flexneri, ATCC 12022 Citrobacter freundii, ATCC 8090 Shigella sonnei, ATCC 25931 Enterobacter aerogenes, ATCC 13048 Staphylococcus aureus, ATCC 25923 Escherichia coli, ATCC 25922 Staphylococcus aureus, (MRSA), Multiply (Methicillin)-Resistant Clinical Isolate Klebsiella pneumoniae, ATCC 13888 Staphylococcus epidermidis, ATCC 12228 Listeria monocytogenes, ATCC 19111 Streptococcus faecalis, ATCC 19433 Mycoplasma gallisepticum, ATCC 19610 Streptococcus pyogenes, ATCC 19615 Pasteurella multocida, ATCC 29977 Proteus vulgaris, ATCC 13315

Process NPD is effective in 3 minutes on hard surfaces against Pseudomonas aeruginosa, ATCC 13388, according to the A.O.A.C. Use Dilution Test when diluted with 400 ppm hard water to make a 1:128 (one ounce per gallon) solution, in the presence of 5% added organic soil (serum).

FUNGICIDE: Passes the A.O.A.C. Fungicidal Test (T. mentagrophytes) when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

\*VIRUCIDE: Process NPD is effective against Herpes Simplex Types 1 and 2, Influenza A2 (Japan-305), Mouse Hepatitis, ATCC VR-764 and Vaccinia Virus, according to the EPA approved virucidal assay method when diluted with 400 ppm hard water to make a 1:256 (one-half ounce per gallon) solution, in the presence of 5% organic soil (serum) in 10 minutes at 20-25°C on hard, non-porous environmental surfaces.

\*VIRUCIDE: Process NPD is effective against the following viruses according to the EPA approved virucidal assay method when diluted with 300 ppm hard water to make a 1:256 (one half ounce per gallon) solution, in the presence of 5% organic soil (serum) in 10 minutes at 20-25°C on hard, non-porous environmental surfaces:

- Canine distemper, ATCC 128 Infectious bronchitis, ATCC VR-22 Canine parainfluenza, ATCC VR-399 Infectious laryngotracheitis, ATCC VR-783 Chlamydia psittaci (Feline Pneumonitis) Marek's Disease, ATCC VR-2002 Feline rhinotracheitis, ATCC VR-636 Newcastle Disease, ATCC VR-109

Effective against Canine parvovirus, ATCC VR-953, Infectious Bursal Disease (Lukert Strain) and Feline calicivirus, ATCC VR-120 according to the EPA approved virucidal assay method when diluted 1:64 (2 ounces per gallon) in 400 ppm hard water (300 ppm for Feline calicivirus) in 5% organic soil (serum) in 10 minutes at 20-25°C on hard, non-porous environmental surfaces.

†When tested by an EPA-approved Dilution Method, the HIV-1(AIDS) virus, with added 5% organic soil (serum), was completely inactivated by a 1:256 (one-half ounce per gallon) solution in 400 ppm A.O.A.C. hard water in 30 seconds at 20°C. Although efficacy at 30 seconds contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 10-minute contact time for disinfection against all of the organisms claimed.

ODOR CONTROL: Eliminates most odors by killing odor-causing bacteria and simultaneously chemically neutralizing their odors. Cleans unpleasant smelling soils.

3/3