

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 11 2004

Mr. Michael Sarli  
Steris Corporation  
7501 Page Avenue  
St. Louis, MO 63133

Subject: Process NPD  
EPA Registration No. 1043-90  
Amendment Date: November 11, 2003  
EPA Receipt Date: November 13, 2003

Dear Mr. Sarli,

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of FIFRA, as amended, is acceptable with the following conditions.

- Response to Agency letter dated March 24, 2003

**Conditions**

Revise the label as follows:

The "First Aid" statements must be organized so that the most severe route of exposure, demonstrated by toxicity category, are listed first. Therefore, the statement must be reorganized as follows: If in eyes, If on skin or clothing, If swallowed, then If inhaled.

**General Comments**

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

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

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.

CONCURRENCES

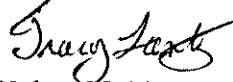
SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



for

Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

Enclosure: Stamped Label

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

**PRECAUTIONARY STATEMENTS  
HAZARD TO HUMANS AND DOMESTIC ANIMALS**

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 (1.5cc) 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 wrung-out applicator. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution when it becomes dirty and replace with a fresh solution. A properly prepared solution with deionized water of Process NPD intended for use as a hard surface disinfectant has a shelf life of 7 days (use life) when stored in a closed container such as a spray bottle. This is a complete product. Do not add other chemicals. Use only as directed.

**ANIMAL HUSBANDRY, ANIMAL RESEARCH, AND POULTRY FACILITY CLEANING AND**

**DISINFECTING:** Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter and manure from the floors, walls, and surfaces of facilities transversed or occupied by animals. Empty all troughs, racks, and other feeding and watering appliance. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use solution of 1/2 oz. per gallon water (1.256 dilution). Apply solution with a cloth, sponge, mop, brush, coarse spray using normal cleaning methods or by fogging following cleaning. Allow surfaces to remain wet for 10 minutes. (For fogging, 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.) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scraper used for removing litter and manure. Ventilate buildings, vehicles, and other closed spaces. Do not house livestock or empty equipment until treatment has absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, and waterers with soap or detergent and rinse with potable water before reuse.

**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.

**VIROCIDAL 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 for fogging (wet misting) as an adjunct following regular cleaning and disinfecting procedures to sanitize surfaces in research and manufacturing facilities. 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.

**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.

**For Control of Witchweed and Broomrape on Farm and Construction Equipment**

**Sites to be Treated**

**Witchweed (*Striga spp.*):** To prevent the spread of Witchweed on items such as water proof boots, vehicles, tires, farm and construction equipment, containers or other equipment taken into infested fields or which may have been exposed to *Striga spp.* or to soil contaminated with *Striga spp.* seeds. Primary expected use will be in the Witchweed Quarantine area, which includes 3 counties in eastern South Carolina and 8 counties in North Carolina.

**Broomrape (*Orobancha spp.*):** To prevent the spread of Broomrape items such as waterproof boots, vehicles, tires, farm and construction equipment, containers or other equipment taken into infested fields or which may have been exposed to *Striga spp.* or to soil contaminated with *Striga spp.* seeds.

**Method and Rate of Application**

To prevent the spread of Witchweed (*Striga spp.*) or Broomrape (*Orobancha spp.*) by this artificial means of transportation, treatments should be made by trigger spraying, dipping or brushing. Thoroughly saturate surfaces with a 1:100 use solution for a period of 1 hour. Allow to air dry. All surfaces that come in contact with food or crop must be rinsed with potable water before reuse. Footwear should be rinsed before reuse. Clothing should be either rinsed or laundered before reuse.

Process NPD will not devitalize seeds contained in seed pods as they are not normally saturated during a standard preventive procedure. Attempt to remove as much plant material as possible before initiating decontamination.

**Process NPD  
One Step Germicidal Detergent  
Germicide Fungicide Virucide  
Detergent/Deodorizer Concentrate**

EPA REG. NO. 1043-90 EPA Est. No. 1043-MO-2

FOR AGRICULTURAL, INDUSTRIAL AND  
INSTITUTIONAL USE ONLY

**Active Ingredients:**

Octyl decyl dimethyl ammonium chloride..... 4.60%  
Dioctyl dimethyl ammonium chloride..... 2.30%  
Didecyl dimethyl ammonium chloride..... 2.30%  
Alkyl (50%C<sub>14</sub>, 40%C<sub>12</sub>, 10%C<sub>16</sub>) dimethyl  
benzyl ammonium chloride..... 6.14%

**Inert Ingredients:**..... 84.66%

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

FIRST AID	
If inhaled	<ul style="list-style-type: none"> <li>•Move person to fresh air.</li> <li>•If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>•Call a poison control center or doctor for further treatment advice.</li> </ul>
If on skin or clothing	<ul style="list-style-type: none"> <li>•Take off contaminated clothing.</li> <li>•Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>•Call a poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul style="list-style-type: none"> <li>•Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.</li> <li>•Call a poison control center or doctor for treatment advice.</li> </ul>
If swallowed	<ul style="list-style-type: none"> <li>•Call poison control center or doctor immediately for treatment advice.</li> <li>•Have person sip a glass of water if able to swallow.</li> <li>•Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>•Do not give anything by mouth to an unconscious person.</li> </ul>
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
MAY 11 2004  
NET CONTENTS:**

**Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 1043-90**

This product is a research-developed 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:

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|---|---|
| <ul style="list-style-type: none"> <li>Acinetobacter calcoaceticus, ATCC 19606</li> <li>Bordetella avium, ATCC 35086</li> <li>Bordetella bronchiseptica, ATCC 10580</li> <li>Campylobacter jejuni, ATCC 29428</li> <li>Candida albicans, Clinical Isolate</li> <li>Candida parapsilosis, Clinical Isolate</li> <li>Citrobacter freundii, ATCC 8090</li> <li>Enterobacter aerogenes, ATCC 13048</li> <li>Escherichia coli, ATCC 25922</li> <li>Klebsiella pneumoniae, ATCC 13883</li> <li>Listeria monocytogenes, ATCC 19111</li> <li>Mycoplasma gallisepticum, ATCC 19610</li> <li>Pasteurella multocida, ATCC 29977</li> <li>Proteus vulgaris, ATCC 13315</li> </ul> | <ul style="list-style-type: none"> <li>Pseudomonas aeruginosa, ATCC 9027</li> <li>Pseudomonas cepacia, ATCC 25669</li> <li>Salmonella enteritidis, ATCC 13076</li> <li>Salmonella typhimurium, ATCC 14028</li> <li>Serratia marcescens, ATCC 8100</li> <li>Shigella flexneri, ATCC 12022</li> <li>Shigella sonnei, ATCC 25931</li> <li>Staphylococcus aureus, ATCC 25923</li> <li>Staphylococcus aureus, (MRSA),<br/>MultiPLY (Methicillin)-Resistant<br/>Clinical Isolate</li> <li>Staphylococcus epidermidis, ATCC 12228</li> <li>Streptococcus faecalis, ATCC 19433</li> <li>Streptococcus pyogenes, ATCC 19615</li> </ul> |
|---|---|

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 A<sub>2</sub> (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:

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|---|---|
| <ul style="list-style-type: none"> <li>Canine distemper, ATCC 128</li> <li>Canine parainfluenza, ATCC VR-399</li> <li>Chlamydia psittaci (Feline Pneumonitis)</li> <li>Feline rhinotracheitis, ATCC VR-636</li> </ul> | <ul style="list-style-type: none"> <li>Infectious bronchitis, ATCC VR-22</li> <li>Infectious laryngotracheitis, ATCC VR-783</li> <li>Marek's Disease, ATCC VR-2002</li> <li>Newcastle Disease, ATCC VR-109</li> </ul> |
|---|---|

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.

**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 rinseate 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.

STERIS Corporation  
7501 Page Avenue  
St. Louis, MO 63133

PRODUCT MADE IN THE U.S.A.

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