

1043-90

3/25/2008

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MAR 25 2008

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

STERIS Corporation
P. O. Box 147
St. Louis, MO 63166-0147

Attention: Jennifer Reeder
Senior Regulatory Affairs Specialist

Subject: Process NPD
EPA Registration No. 1043-90
Notification Dated March 11, 2008

This will acknowledge receipt of your notification for the addition of a one ounce package size, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely

A handwritten signature in cursive script that reads "Martha R. Terry / 703".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510P)

33
STERIS[®] 2/4



CERTIFIED MAIL# 7006 2760 0000 6889 2298

March 11, 2008

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460
Attn: Marshall Swindell, PM#33

Re: Notification of new package size for Process NPD (EPA Reg. No. 1043-90)

Dear Mr. Swindell:

Enclosed in support of the subject action please find the following:

- Application for Pesticide (EPA Form 8570-1)
- Process NPD master label

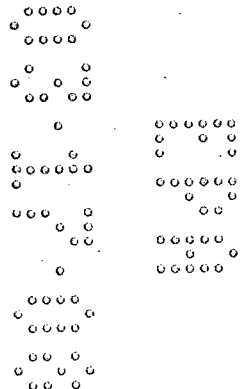
We request the addition of the one ounce package size.

If you have any questions, I can be reached at 314-290-4705.

Sincerely,

Jennifer Reeder
Sr. Regulatory Affairs Specialist

Enclosures



STERIS Corporation • P.O. Box 147 • St. Louis, MO 63166-0147 • USA • 314-290-4600

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United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1043-90	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Process NPD	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) STERIS Corporation P.O. Box 147 St. Louis, MO 63133-0147 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____
 Resubmission in response to Agency letter dated _____ "Me Too" Application.
 Notification - Explain below. Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of new package size for Process NPD. Clarification of equivalent dilution for the use of the new 1 oz. package size. No other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is in violation of 18 U.S.C. Section. 1001 to willfully make any false statements to the EPA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt. 1 oz.	No. per container 144	If "Yes" Package wgt.	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1oz, 1qt, 1gal, 5gal, 55gal	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product			
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jennifer Reeder	Title Sr. Regulatory Affairs Sp	Telephone No. (Include Area Code) 314 290 4705
2. Signature <i>Jennifer Reeder</i>		3. Title Sr. Regulatory Affairs Specialist
4. Typed Name Jennifer Reeder		5. Date March 11, 2008
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)

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 (15cc) to each measured gallon of water used. Add 1 oz. (29.1 mL) to 2 gallons 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 coarse 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.

VRUCIDAL ACTIVITY AGAINST CANINE PARVOVIRUS, FELINE CALCIVIRUS AND INFECTIONOUS 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 of 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%C₁₄, 40%C₁₂, 10%C₁₆) dimethyl benzyl ammonium chloride.....6.14%
Inert Ingredients:.....84.66%

KEEP OUT OF REACH OF CHILDREN
DANGER

FIRST AID	
If in eyes	<ul style="list-style-type: none"> •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 the eye. •Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> •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	<ul style="list-style-type: none"> •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	<ul style="list-style-type: none"> •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.
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.	

NET CONTENTS:

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, non-porous environmental surfaces such as floors, walls, counters, tools, cars, 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),
Klebsiella pneumoniae, ATCC 13883	Multiply (Methicillin)-Resistant
Listeria monocytogenes, ATCC 19111	Clinical Isolate
Mycoplasma gallisepticum, ATCC 19610	Staphylococcus epidermidis, ATCC 12228
Pasteurella multocida, ATCC 29977	Streptococcus faecalis, ATCC 19433
Proteus vulgaris, ATCC 13315	Streptococcus pyogenes, ATCC 19615

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 calcivirus, 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 calcivirus) 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 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.

STERIS Corporation
7501 Page Avenue
St. Louis, MO 63133

PRODUCT MADE IN THE U.S.A.

h/h