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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

FEB - 3 2010

Mr. Michael G. Sarli
Lead Regulatory Specialist for,
Steris Corporation
P. O. Box 147
Saint Louis, MO 63166-0147

Subject: Process NPD
EPA Registration Number 1043-90
Your Amendment Dated January 4th, 2009
EPA Received Date January 5th, 2009

The amendment referred to above, submitted in connection with the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to revise the container disposal language as per PR Notice 2007-4, is acceptable.

The notification has been part of the permanent record of this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Karen M. Leavy-Munk for,
Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division (7510P)

STERIS®

January 4, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Regulatory Management Branch 1
Antimicrobials Division (7510C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
Attn: Velma Noble, PM #31

Re: Notification for Process NPD (EPA Reg. No. 1043-90) submitted 11/12/09
Revision of Container Disposal Language in Compliance with PR Notice 2007-4
Your Letter Dated December 11, 2009

Dear Ms. Noble:

In your response to our notification of 11/12/09 to add Container Disposal statements in compliance with PR Notice 9007-4, you indicate that language does not provide for residue removal for the packet. Since the packet is a non-rigid container, it is our understanding that the language provided was adequate. The AD has approved the same language for packets for EPA Reg. No. 1043-91, 1043-114 and 1043-115.

Please advise if our understanding is in error and clarify what standardized removal language is appropriate for a non-rigid, non-refillable packet.

If you have any questions I can be reached at 314-290-4704 or at mike_sarli@steris.com.

Sincerely,

Michael G. Sarli
Lead Regulatory Specialist
STERIS Corporation

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_{14}, 40%C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride	6.14%
Inert Ingredients:	84.66%
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER

FIRST AID	
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 the 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 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.
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:

STERIS Corporation
7501 Page Avenue
St .Louis, MO 63133

PRODUCT MADE IN THE U.S.A.

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.

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
Bordetella avium, ATCC 35086
Bordetella bronchiseptica, ATCC 10580
Campylobacter jejuni, ATCC 29428
Candida albicans, Clinical Isolate
Candida parapsilosis, Clinical Isolate
Citrobacter freundii, ATCC 8090
Enterobacter aerogenes, ATCC 13048
Escherichia coli, ATCC 25922
Klebsiella pneumoniae, ATCC 13883
Listeria monocytogenes, ATCC 19111
Mycoplasma gallisepticum, ATCC 19610
Pasteurella multocida, ATCC 29977
Proteus vulgaris, ATCC 13315
Pseudomonas aeruginosa, ATCC 9027
Pseudomonas cepacia, ATCC 25609
Salmonella enteritidis, ATCC 13076
Salmonella typhimurium, ATCC 14028
Serratia marcescens, ATCC 8100
Shigella flexneri, ATCC 12022
Shigella sonnei, ATCC 25931
Staphylococcus aureus, ATCC 25923
Staphylococcus aureus, (MRSA),
Multiply (Methicillin)-Resistant
Clinical Isolate
Staphylococcus epidermidis,ATCC 12228
Streptococcus faecalis, ATCC 19433
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 A_2 (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.

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

or

Kills Pandemic 2009 H1N1 influenza A virus formerly called swine flu.

***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
Canine parainfluenza, ATCC VR-399
Chlamydia psittici (Feline Pneumonitis)
Feline rhinotracheitis, ATCC VR-636
Infectious bronchitis, ATCC VR-22
Infectious laryngotracheitis, ATCC VR-783
Marek's Disease, ATCC VR-2002
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 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.

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 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 HUSBNDRY, 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 transverse 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 ½ oz. per gallon water (1:256 dilution). Apply solution with a cloth, sponge, mop, brush or coarse spray using normal cleaning methods or be fogging following cleaning. Allow surfaces to remain wet for 10 minutes. (For fogging, fog the desired area at 32 to 64 fluid ounces of use dilution per 1,000 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 wit waterproof coverings.) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate building, 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.

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

FOGGINH 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 fluid ounces of use dilution per 1,000 cubic feet using equipment with an automated 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 Withcweed Quarantine area, which includes 3 counties in eastern South Carolina and 8 counties in North Carolina.
Broomrape (*Orobanche 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 Withchweed (*Striga spp.)* or Broomrape (*Orobanche 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.

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 or 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:
(For Packet:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.
(For ≤5 gal:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.
(For > 5 gal.): Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.