

1043-126

12-14-2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 1043-126
Date of Issuance: DEC 14 2011

Term of Issuance: Conditional

Name of Pesticide Product: EXP 10006

NOTICE OF PESTICIDE:
[x] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):
Steris Corporation,
7501 Page Avenue
S Louis, MO 63133

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(a) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling change listed below before you release the product for shipment:

(a) Revise the EPA Registration Number to read, "EPA Reg. No. 1043-126

Signature of Approving Official:
Velma Noble
Product Manager Team-31
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date: DEC 14 2011

EPA Form 8570-6

CONCURRENCES

Table with columns for SYMBOL, EPA Reg. No., SURNAME, and DATE. EPA Reg. No. is 1043-126.

(b) The Confidential Statement of Formula (CSF), dated 07/26/11, for the basic formulation, is acceptable. The OPPTS 830 guidelines Groups "A & B" product chemistry data requirements applicable to end-use products have been met, with the exception of the OPPTS 830.6317 "Storage Stability" and 830.6320 "Corrosion Characteristics".

(c) The following revisions to the product label are recommended:

- Under the "Container Disposal" section on the product label, identify disposal options for the packet using the following (or similar text): "or dispose of packet in trash."
- Under the "Precautionary Statements" section on the product label, change "after handling and before eating, drinking, or using tobacco" to read "after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."
- Place the "Storage and Disposal" section on the product label in a text box for prominence.
- Under the Storage and Disposal Statements, change the Storage subheading to read "Pesticide Storage."
- Under the "Pesticide Storage" section on the product label, add instructions that specify what to do if the product leaks or spills from the product container.

(d) Your claims for the use of this product as a fog to sanitize are not acceptable. Currently, the Agency does not have a protocol to support the sanitizing of surfaces via a fogging claim. These directions are false and misleading to consumers by giving an impression that product is offering an additional layer of safety against microorganisms. Delete the "Fogging as an Adjunct to regular cleaning and disinfecting" section of this label.

(e) The signal word is **DANGER**.

1. The precautionary labeling must read, "**Corrosive**. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. May be fatal if inhaled. Harmful if swallowed. Do not breathe vapor or spray mist. Wear coveralls worn over long-sleeved shirt and long pants, socks, chemical-resistant footwear, and natural rubber gloves. Wear goggles, face shield, or shielded safety glasses. Wear a respirator with an organic vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC -23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P, or HE prefilter. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

2. The current first aid statements must read:

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.

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.
- Call a poison control center or doctor for treatment advice.

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If inhaled: UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

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 by a poison control center or doctor
- Do not give anything by mouth to an unconscious person.

3. **"Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage." must appear on the label.

4. This product meets the criteria to be labeled as a Restricted-Use Pesticide base on the waivers for skin irritation and eye irritation. This product must be packaged in CRP (Child Resistant Packaging).

(f) The following revision to the proposed label must be made:

- Under the "Cleaning and Disinfecting" directions on page 3 of the proposed label, change "2 fl. oz. to 2 gallons of water" to read "2 fl. oz. to 1 gallon of water".
- On page 2 of the proposed label, change "tile" to read "glazed tile". Tile is a porous surface.
- On page 3 of the proposed label, change "NON-PORUS" to read "NON-POROUS".
- On page 3 of the proposed label, change "course spray" to read "coarse spray".
- On page 3 of the proposed label, change "wrung-out applicator" to read moist or damp applicator".
- On page 3 of the proposed label, change "Remove gross filth mechanically by sweeping." to read "Remove gross filth mechanically by sweeping or other appropriate cleaning techniques" and move this statement closer to the beginning of the directions before instruction of application of solution.
- On page 3 of the proposed label, change "HUSBNDRY" to read "HUSBANDRY".
- On page 4 of the proposed label, change "one fluid ounce per gallon" to read "one fluid ounce per gallon".
- On page 5 the virus Pandemic 2009 H1N1 influenza A virus is listed twice for intended listing of different viral strains that the product is effective against.
- "A properly prepared solution with deionized water of this product intended for use as a hard surface disinfectant has a shelf life of 35 days (use life) when stored in a closed container such as a spray bottle" to read "A properly prepared solution with water of this product intended for use as a hard surface disinfectant. The shelf life is 35 days (use life) when stored in a closed container such as a spray bottle."

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

A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Velma Noble at (703) 308-308-6233 Jamil Mixon at (703) 308-8032.

Sincerely,



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

Enclosures: Stamped Label

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EXP 10006

Disinfectant Fungicide Virucide Detergent Deodorizer Concentrate

EPA REG. NO. 1043-REA EPA Est. No. 1043-MO-2
EPA Ext. 11563-MI-1

FOR INDUSTRIAL AND INSTITUTIONAL USE

Active Ingredients:

Didecyl dimethyl ammonium chloride

10.5%

Inert Ingredients:

89.5%

Total:

100.0%

**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.	

See (side) (back) panel for additional precautionary statements.

NET CONTENTS:

STERIS Corporation
7501 Page Avenue
St. Louis, MO 63133
www.steris.com

PRODUCT MADE IN THE U.S.A.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 14 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 10324-126

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS:

DANGER: Corrosive. Causes irreversible eye damage and skin burns. 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, chewing gum, using tobacco, or using the toilet. 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 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 hard, non-porous surfaces such as metal surfaces such as stainless or galvanized steel and chrome, glazed porcelain, plastics, glass, glazed tile, washable painted or varnished surfaces, sealed concrete, as well as resilient vinyl, asphalt, noleum, rubber, terrazzo or other combination-type floors.

DISINFECTANT: This product is effective in 10 minutes on hard, non-porous surfaces against *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538), and *Salmonella enterica* (ATCC 10708) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (one fluid ounce per gallon) solution, in the presence of 5% organic soil (serum) at 20°C.

FUNGICIDE: This product is effective against *Trichophyton mentagrophytes* (ATCC 9533) and *Aspergillus niger* (ATCC 6275) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (one fluid ounce per gallon) solution, in the presence of 5% organic soil (serum), for a contact time of 10 minutes at 20°C. This product is effective against *Aspergillus Brasiliensis* (ATCC 16404) when diluted with 400 ppm A.O.A.C. hard water to make a 1:64 (two fluid ounces per gallon) solution, in the presence of 5% organic soil (serum), for a contact time 10 minutes at 20°C.

***VIRUCIDE:** This product is effective against Human Influenza A2 Virus (A/2/Japan/305/57) (H2N2) (Clinical Isolate), and Human Immunodeficiency Virus Type 1 (HIV-1) (Clinical Isolate), when diluted with 400 ppm hard water to make a 1:128 (one fluid ounce per gallon) solution, in the presence of 5% organic soil (serum) for a contact time 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 (formerly called swine flu).

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ODOR CONTROL: This product eliminates many odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors and leaving a pleasant fragrance. Follow **"CLEANING AND DISINFECTING HARD, NON-POROUS SURFACES"** directions.

PRODUCT CLAIMS	
Broad Spectrum Disinfectant [<i>Staphylococcus aureus</i> (ATCC 6538), <i>Salmonella enterica</i> (ATCC 10708), <i>Pseudomonas Aeruginosa</i> (ATCC 15442)] <i>Aspergillus niger</i> (ATCC 6275) <i>Trichophyton mentagrophytes</i> (ATCC 9533) *HIV-1** (Clinical Isolate) *Human Influenza A2 Virus (A/2/Japan/305/57) (H2N2) (Clinical Isolate)	1:128 dilution in 400 ppm hard water at 10 minutes 20°C in the presence of 5% organic soil (serum)
<i>Aspergillus brasiliensis</i> (ATCC 16404)	1:64 dilution in 400 ppm hard water at 10 minutes 20°C in the presence of 5% organic soil (serum)
Broad Spectrum Disinfectant [<i>Staphylococcus aureus</i> (ATCC 6538), <i>Salmonella enterica</i> (ATCC 10708), <i>Pseudomonas aeruginosa</i> (ATCC 15442)]	1:128 dilution (up to 5 weeks old) in deionized water at 10 minutes 20°C in the presence of 5% organic soil (serum)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

CLEANING AND DISINFECTING HARD, NON-POROUS SURFACES: Add one fluid ounce of product to each measured gallon of water used. (or Add 2 fl. oz. to 2 gallon of water used.) For *Aspergillus brasiliensis*, add two fluid ounces of product to each measured gallon of water used. Always add this product to pre-measured water. Gently mix for a uniform solution. Remove gross filth mechanically by sweeping or other appropriate cleaning techniques. 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 moist or damp applicator. Discard solution when it becomes dirty and replace with a fresh solution. **A properly prepared solution with water of this product intended for use as a hard surface disinfectant has a shelf life of 35 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 fl. oz. per gallon water (1:128 dilution). Apply solution with a cloth, sponge, mop, brush or 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 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 with 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 fluid 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.

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 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 and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of a 1:128 use-solution (one fluid ounce per gallon). Prepare and apply solution as directed in paragraphs above.

Contact Time: Allow surface to remain wet for 10 minutes.

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 food, feed, or water by storage or disposal.

Storage: Do not store near heat or open flame. If frozen, thaw and remix before use.

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.

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 or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents and dispose of as pesticide waste. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as pesticide waste. Drain for 10

seconds after the flow begins to d Repeat this procedure two more t is.

(For > 5 gal.): Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents and dispose of as pesticide waste. Fill the container 1/4 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. Dispose of rinsate as pesticide waste. Repeat this procedure two more times.

