

1043-126

9/25/2013

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

Resa J. Manson
Manager Regulatory Affairs
Steris Corporation
P/O Box 147
ST. Louis, MO 63166-0147

SEP 25 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SUBJECT: Vesta-Syde SQ Quaternary Ammonium Disinfectant
EPA Registration No. 1043-126
Application Dated: June 25, 2013
Receipt Date: July 1, 2013

Dear Ms. Manson:

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

- To clarify the use direction language for viruses and fungicides
- To delete fogging applications for animal husbandry, animal research and poultry facility cleaning and disinfection.

Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data. A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulation at 40 CFR 152.3.

General Comments

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,

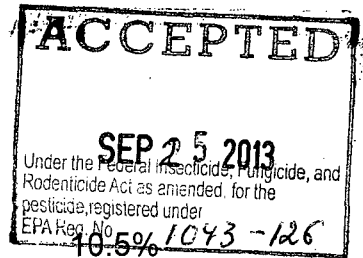
Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

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Vesta-Syde SQ Quaternary Ammonium Disinfectant

Disinfectant Fungicide Virucide* Detergent Deodorizer Concentrate

EPA REG. NO. 1043-126 EPA Est. No. 1043-MO-2
EPA Ext. 11563-MI-1



FOR INDUSTRIAL AND INSTITUTIONAL USE

Active Ingredients:

Didecyl dimethyl ammonium chloride

Inert Ingredients:

Total:

10.5%
89.5%
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. •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 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.
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.
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 panel)(back panel)(insert) for additional (precautionary statements) (directions for use).

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:

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Harmful if swallowed or inhaled. Avoid breathing spray mist or vapor. 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. 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 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, linoleum, rubber, terrazzo or other combination-type floors.

DISINFECTANT: This product is effective in 10 minutes at 20°C on hard, non-porous surfaces, in the presence of 5% organic soil when diluted as given below with 400 ppm A.O.A.C. hard water as: Disinfectant against *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538), and *Salmonella enterica* (ATCC 10708) when diluted to make a 1:128 (one fluid ounce per 1 gallon of water) solution; Virucidal* when diluted to make a 1:128 (one fluid ounce per 1 gallon) solution; Fungicidal against *Trichophyton mentagrophytes* (ATCC 9533) and *Aspergillus niger* (ATCC 6275) when diluted to make a 1:128 (one fluid ounce per 1 gallon) solution and against *Aspergillus brasiliensis* (ATCC 16404) when diluted to make a 1:64 (two fluid ounces per 1 gallon) solution.

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 1 gallon) solution, in the presence of 5% organic soil, 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 1 gallon) solution, in the presence of 5% organic soil, for a contact time of 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 1 gallon) solution, in the presence of 5% organic soil 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).

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
<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
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

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 1 gallon of water used. For *Aspergillus brasiliensis*, add two fluid ounces of product to each measured 1 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 is 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.** 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 traversed 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 one fluid ounce per 1 gallon water (1:128 dilution). Apply solution with a cloth, sponge, mop, brush or coarse spray using normal cleaning methods. Allow surfaces to remain wet for 10 minutes. (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 1 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 FOR REGULAR CLEANING: This product may be used for fogging (wet misting) following regular cleaning procedures 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 1 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.

Pesticide 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 or dispose of packet in trash.

(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 ¼ full with water and recap. Shake for 10 seconds. Dispose of rinsate as pesticide waste. 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 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 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. Dispose of rinsate as pesticide waste. Repeat this procedure two more times.

(Optional Label Text:)
(STERILE UNLESS PACKAGING IS COMPROMISED)