



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 10, 2018

Jennifer Pavlovsky
Manager Regulatory Affairs
STERIS Corporation
P.O. Box 147
St. Louis, MO 63166-0147

Subject: Label Amendment – Update Precautionary Statements and Personal Protective Equipment
Product Name: Vesta-Syde SQ 128 Ready-To-Use Disinfectant
EPA Registration Number: 1043-130
Application Date: 07/25/2018
Decision Number: 543128

Dear Ms. Pavlovsky:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one 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 its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Jake Farley by phone at (703) 347-0123, or via email at Farley.jake@epa.gov.

Sincerely,



Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

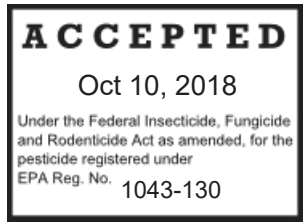
Vesta-Syde SQ 128 Ready-To-Use Disinfectant

One-Step Cleaner-Disinfectant-Fungicide-Virucide*

EPA REG. NO. 1043-130

EPA Est. No. 1043-M0-2 - EPA Est. No. 11563-MI-1

FOR INDUSTRIAL AND INSTITUTIONAL USE



Active Ingredients:

Didecyl dimethyl ammonium chloride 0.08%

Isopropyl alcohol 10.00%

Other Ingredients: 89.92%

Total: 100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID

In case of emergency, call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

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 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.

REORDER NUMBER: () NET CONTENTS: ()

Manufactured by:

STERIS Corporation

7501 Page Avenue

St. Louis, MO 63133

PRODUCT MADE IN THE U.S.A.

See (side panel) (back panel) (insert) for additional (precautionary statements) (directions for use).

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wear long-sleeved shirt, long pants, socks, shoes and waterproof or chemical-resistant gloves when handling. 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.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.



This ready-to-use product is intended for use on washable hard, non-porous environmental surfaces such as floors, walls, counters, tools, carts, and other medical equipment surfaces used in pharmaceutical and cosmetic manufacturing facilities, and in food processing, preparation and service facilities, in veterinary clinics, animal research facilities, and in other indoor areas.

Use this product for cleaning and disinfection of hard, non-porous surfaces such as metal surfaces made of 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 ready-to-use product is effective in 10 minutes at 20°C on washable hard, non-porous surfaces, in the presence of 5% organic soil against the following: **Bacteria:** *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538), *Staphylococcus epidermidis* (ATCC 12228), *Burkholderia cepacia* (ATCC 25416), *Enterobacter cloacae* (ATCC 13047), *Streptococcus pyogenes* (ATCC 19615), *Listeria monocytogenes* (ATCC 19111), *Micrococcus yunnanensis* (ATCC 7468), *Serratia marcescens* (ATCC 14756) and *Mycoplasma gallisepticum* (ATCC 15302). **Fungi:** *Trichophyton interdigitale* (ATCC 9533) and *Candida albicans* (ATCC 10231), ***Viruses:** Influenza A2 Virus (A/2/Japan/305/57) (H2N2)*, Human Immunodeficiency Virus Type 1 (HIV-1)* and Avian Influenza (H9N2) Virus*.

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.

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:

Remove gross filth mechanically by sweeping or other appropriate cleaning techniques. Apply this ready-to-use product with a cloth, sponge, mop, brush, or coarse spray using normal cleaning methods. Thoroughly wet all surfaces to be cleaned. Treated surfaces must remain visibly wet for 10 minutes. Then remove excess solution with a moist or damp applicator.

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 appliances. Thoroughly clean all surfaces with soap or

detergent and rinse with water. Apply product to hard, non-porous surfaces with a cloth, sponge, mop, brush, or coarse spray using normal cleaning methods. Saturate surfaces with product. Treated surfaces must remain visibly 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 visible soil. Thoroughly wet all hard, non-porous surfaces. Scrub to loosen all soils. Surface must remain visibly wet for 10 minutes. Thoroughly rinse all wetted and cleaned surfaces with potable water.

***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: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application. Apply solution as directed in paragraphs above.

Contact Time: Allow surface to remain visibly 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: Store in original container in a cool, well-ventilated area. 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 < 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 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 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.

Optional Label Text is enclosed in parentheses.
(STERILE UNLESS PACKAGING IS COMPROMISED)