

1043-114

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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4/4/2011



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

APR - 4 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Mike Sarli
STERIS Corporation
PO Box 147
St. Louis, MO 63166-0147

Subject: Vesta-Syde
EPA Registration No.: 1043-114
Amendment Date: January 28, 2011
EPA Receipt Date: January 30, 2011

Dear Mr. Sarli:

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with conditions.

Proposed Amendment

- Adding establishment number and container sizes
- Updating organism nomenclature and precautionary statements

Conditions

Revise the label as follows:

Revise the last statement in the paragraph above the ingredient's statement to read "*Do not store instruments in the decontamination solution.*"

General Comments

A stamped copy of the accepted label with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

If you have further questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Glen McLeod by telephone at (703) 347-0181 or by email at mcLeod.glen@epa.gov. When you are submitting

information or data in response to this letter send a copy of this letter to accompany the submission in order to facilitate processing.

CONCURRENCES					
SYMBOL					
SURNAME					
DATE					

Sincerely,

Jacqueline Campbell-McFarlane

Jacqueline Campbell-McFarlane
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: Stamped Label

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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VESTA-SYDE®

INTERIM INSTRUMENT
DECONTAMINATION SOLUTION

EFFECTIVE IN THE PRESENCE OF SERUM AND HARD WATER
For Interim Instrument Decontamination prior to Terminal
Cleaning and Sterilization of Surgical Instruments and
Apparatus...Use only with Vesta-Syde Enzyme Presoak.
Do not add other chemicals. Not recommended for
prolonged storage of instruments.

FOR INSTITUTIONAL USE

Active Ingredients:

o-phenylphenol.....9.09%

p-tertiary amyphenol.....7.66%

Inert Ingredients.....83.25%

Total100.00%

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.	

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS: DANGER

Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed, inhaled or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or face shield), protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco or using the toilet.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

DIRECTION FOR USE

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

DECONTAMINATING SOILED SURGICAL INSTRUMENTS AND APPARATUS: This product is formulated for use in conjunction with Vesta-Syde Enzyme Presoak. Vesta-Syde Enzyme Presoak should be diluted 2 ounces per gallon of water (1:64) and a minimum 20 minute exposure time should be allowed for the Enzyme Presoak to work sufficiently to loosen proteinaceous soils. After a minimum 20 minute exposure to Vesta-Syde Enzyme Presoak, 2 ounces per gallon (1:64) of Vesta-Syde Instrument Decontamination Solution should be deposited in the same vessel holding the soiled instruments and enzyme presoak solution. Gently stir the solution to provide a uniform mixture and thorough contact with the treated surfaces. Allow a minimum 20 minutes contact time to achieve interim instrument decontamination on all soiled instruments and apparatus deposited in the vessel. Avoid splashing and cover, where possible, when transporting soiled instruments.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care 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 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF 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 solution (1 fl. oz. per gallon). Prepare and apply solution as directed in paragraph above.
Contact Time: While the HIV-1 virus is inactivated in 1 minute, use a 20-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.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.
PESTICIDE STORAGE: Store in original container in areas inaccessible to persons unfamiliar with its use.
PESTICIDE DISPOSAL: Pesticide waste may be acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these waste 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: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If not, puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities.

STERIS Corporation

7501 Page Avenue
St. Louis, MO 63133 U.S.A.
800-548-4873 www.steris.com

ACCEPTED No. 1043-114
with COMMENTS
RETCENTENTS:

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

APR - 4 2011

PRODUCT MADE IN U.S.A.

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

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VESTA-SYDE® INTERIM INSTRUMENT DECONTAMINATION SOLUTION PACKAGE INSERT

VESTA-SYDE INTERIM INSTRUMENT DECONTAMINATION SOLUTION represents a research-developed, state of the art compound for use with Vesta-Syde Enzyme Presoak as part of an interim instrument decontaminating step for soiled surgical instruments and apparatus. It substantially reduces the risk of exposure once surgery is completed. This product is effective in both hard water and in the presence of 5% blood serum. It is formulated as a concentrate for use in conjunction with the enzyme presoak. Its unique formulation allows for the addition of this product into the soiled instrument container in surgical suits or other procedure areas

Although efficacy was shown at various dilutions and contact times, use this product at a 1:64 dilution for a 20 minute contact time for use against all of the organisms claimed.

GERMICIDAL: Passes A.O.A.C. Germicidal Use-Dilution Method (*S. aureus*, *S. choleraesuis*, *Ps. aeruginosa*) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

INTERIM INSTRUMENT DECONTAMINATION/DISINFECTION PRIOR TO TERMINAL CLEANING AND STERILIZATION TO REDUCE THE RISK OF CROSS CONTAMINATION: When tested according to a protocol which comprised simulated contamination of instruments with a slurry containing proteinaceous matter derived from beef tissue and sheep's blood (50% by volume) containing A.O.A.C. specified concentrations of *S. aureus*, *S. choleraesuis*, and *Ps. aeruginosa* dried then exposed to Vesta-Syde Enzyme Presoak diluted 1:64 dilution in 400 ppm A.O.A.C. hard water for 20 minutes followed by the addition of Vesta-Syde Interim Instrument Decontamination Solution at a 1:64 dilution in the enzyme presoak solution completely inactivated *S. aureus*, *S. choleraesuis*, and *Ps. aeruginosa* in replicate tests in 20 minutes at 25°C (room temperature).

BROAD SPECTRUM DATA: In addition, the following organisms pass the A.O.A.C. Use-Dilution Test in 400 ppm A.O.A.C. hard water at a dilution of 1:128 in the presence of 5% organic soil (serum), 10 minutes at 20°C.

- | | |
|--|--|
| Acinetobacter calcoaceticus, ATCC 19606 | Proteus vulgaris, ATCC 13315 |
| Candida albicans, Clinical Isolate | Pseudomonas aeruginosa, ATCC 27853 |
| Candida parapsilosis, Clinical Isolate | Pseudomonas cepacia, ATCC 25416 |
| Citrobacter freundii, ATCC 8090 | Salmonella typhi, ATCC 6539 |
| Enterobacter aerogenes, ATCC 13048 | Salmonella typhimurium, ATCC 14028 |
| Enterobacter cloacae, ATCC 23355 | Serratia marcescens, ATCC 8100 |
| Escherichia coli, ATCC 25922 | Shigella flexneri, ATCC 12022 |
| Klebsiella pneumoniae, ATCC 13883 | Shigella sonnei, ATCC 25931 |
| Staphylococcus aureus, (MRSA),
Multiply (Methicillin)-Resistant
Clinical Isolate | Staphylococcus aureus, ATCC 25923 |
| Proteus mirabilis, Clinical Isolate | Staphylococcus epidermidis, ATCC 12228 |
| | Streptococcus faecalis, ATCC 19433 |
| | Streptococcus pyogenes, ATCC 19615 |

Vesta-Syde Interim Instrument Decontamination Solution is effective in 3 minutes at 20°C 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 1:64 (2 ounces per gallon) solution, in the presence of 5% added organic soil (serum).

FUNGICIDAL: Passes A.O.A.C. Fungicidal Test (*T. Mentagrophytes*) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

TUBERCULOCIDAL: Passes A.O.A.C. Tuberculocidal Test (*Mycobacterium tuberculosis*, var. *bovis*) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

VIROCIDAL: Passes Virucidal Assay (AOAC Use Dilution Method) [Influenza A₂ (Japan) virus, Herpes Simplex Type 2 virus, Vaccinia virus, Adenovirus Type 2 virus, Avian Infectious Bronchitis virus, Avian Laryngotracheitis virus, Avian Newcastle Disease virus, and Porcine Pseudorabies virus], when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution in the presence of 5% organic soil (serum) in 10 minutes at 20°C.

†When tested by an AOAC Use Dilution Method, the HIV-1(AIDS) virus, with added 10% organic soil (serum), was completely inactivated by a 1:128 (1 ounce per 1 gallon) solution in 400 ppm A.O.A.C. hard water in 60 seconds at 20-25°C. Although efficacy at 1 minute contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 20-minute contact time for disinfection against all of the organisms claimed.

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.

ODOR CONTROL: It eliminates many odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors and leaving a pleasant fragrance.