1043-114 5/4/2011 1 of 5

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, DC 20460**

MAY - 4 2011

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Michael G. Sarli, Manager
Regulatory Affairs
Steris Corporation
P.O. Box 147
St. Louis, MO 63166-0147

Subject: Notification per PR Notice 98-10
Vesta Syde Interim Instrument Decontamination Solution
EPA Registration Number: 1043-114
Application Date: April 25, 2011
Application Receipt: April 26, 2011

Dear Mr. Sarli:

This acknowledges receipt of your notification, submitted under the provisions of FIFRA section 3(c) 9 and PR Notice 98-10.

**Proposed Notification:**

Steris Corporation is updating the labeling claims nomenclature and revising the label language to comply with PR Notice 2000-5.

**General Comments:**

Based on a review of the submitted materials, your notification of minor label revisions is acceptable. A copy of this letter has been made a part of the permanent record for 1043-114.

If you have 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 Killian Swift by telephone at (703) 308-6346 email address at: swift.killian@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.

Sincerely,

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

| EPA | United States Environmental Protection Agency<br>Washington, DC 20460 | Registration<br>Amendment<br>X Other | OPP Identifier Number |
|---|---|---|---|

## Application for Pesticide - Section I

| 1. Company/Product Number 1043-114 | 2. EPA Product Manager<br>Jacqueline Campbell-McFarlane | 3. Proposed Classification |
|---|---|---|
| 4. Company/Product (Name)<br>Vesta-Syde Interim Instrument Decontamination Solution | PM # 34 | X None Restricted |
| 5. Name and Address of Applicant (include Zip Code)<br>STERIS Corporation<br>P.O. Box 147<br>St. Louis, MO 63166-0147<br>Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:<br>EPA Reg. No.<br>Product Name | |

## Section - II

| | |
|---|---|
| Amendment - Explain Below | Final printed labels in response to Agency letter dated |
| Resubmission in response to Agency letter dated_____ | "Me Too" Applicaton |
| X Notification – Explain below. | Other – Explain below. |

**Explanation: Notification of minor additions to labeling as per PR Notice 98-10**
"This notification is consistent with the provisions of PR Notice 98-10 and EPA Regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

## Section - III

**1. Material This Product will be Packaged In:**

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| Yes* | Yes | Yes | Metal |
| X No | No X | No X | Plastic |
| | | | Glass |
| *Certification must be submitted | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | Paper<br>X Other (Specify) Foil packet |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| Label X Container | 1 fl. oz., 2 fl. oz. and 1 gallon | On Label X<br>On Labeling accompanying product |

| 6. Manner in Which Label is Affixed to Product | | |
|---|---|---|
| | Lithograph X | Other |
| | Paper glued | |
| | Stenciled | |

## Section - IV

**1. Contact Point** (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Michael G. Sarli | Manager Regulatory Affairs | 314-290-4704 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| 2. Signature | 3. Title | 6. Date Application Received (Stamped) |
|---|---|---|
| Michael G. Sarli | Manager Regulatory Affairs | |
| 4. Typed Name<br>Michael G. Sarli | 5. Date<br>4/25/11 | |

STERIS®

April 25, 2011

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Regulatory Management Branch II
Antimicrobials Division (7510C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
Attn: Jacqueline Campbell-McFarlane, PM Team 34

Re: Notification for Vesta-Syde Interim Instrument Decontamination Solution (EPA Reg. No. 1043-114 – Minor Additions to Labeling in Accordance with PR Notice 98-10

Dear Ms. McFarlane:

Enclosed in support of the subject action, please find the following:

- Application for Pesticide (EPA Form 8570-1)
- Labeling (1 copy)

Revisions were incorporated into the labeling form the EPA approval of amendment dated 4/4/11. In addition, reference to *Salmonella choleraesuis* has been changed to *Salmonella enterica* and statements of "should" have been changed to "is to" in the Directions for Use.

If you have any questions I can be reached at 314-290-4704 or at mike_sarli@steris.com or Mike Ebers at 314-290-4701 or at mike_ebers@steris.com

Sincerely,

Michael G. Sarli
Regulatory Affairs
STERIS Corporation

Enclosures

# 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. Do not store instruments in the decontamination solution

**FOR INSTITUTIONAL USE**

**Active Ingredients:**

| | |
|---|---|
| o-phenylphenol | 9.09% |
| p-tertiary amylphenol | 7.66% |
| **Inert Ingredients** | 83.25% |
| 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.<br>•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.<br>•Call a poison control center or doctor for treatment advice. |
| If on skin or clothing | •Take off contaminated clothing.<br>•Rinse skin immediately with plenty of water for 15-20 minutes.<br>•Call a poison control center or doctor for treatment advice. |
| If swallowed | •Call poison control center or doctor immediately for treatment advice.<br>•Have person sip a glass of water if able to swallow.<br>•Do not induce vomiting unless told to do so by the poison control center or doctor.<br>•Do not give anything by mouth to an unconscious person. |
| If inhaled | •Move person to fresh air.<br>•If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.<br>•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.**

NOTIFICATION
Date Reviewed: 2/4/11
Reviewed By: K Smyth

## 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 is to be diluted 2 ounces per gallon of water (1:64) and a minimum 20 minute exposure time is to 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 is to 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

EPA Reg. No. 1043-114

EPA Est. No. 11583-MI-1
EPA Est. No. 1043-MO-2

**NET CONTENTS:**

PRODUCT MADE IN U.S.A.

DRAFT 4/25/11

# 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. enterica, 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 |
| | Staphylococcus epidermidis, ATCC 12228 |
| | Streptococcus faecalis, ATCC 19433 |
| Proteus mirabilis, Clinical Isolate | 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.

**VIRUCIDAL:** Passes Virucidal Assay (AOAC Use Dilution Method) [Influenza $A_2$ (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.

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