

1043-114

12/1/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

DEC 1 2009

Michael G. Sarli  
Lead Regulatory Specialist  
Steris Corp.  
P.O. Box 147  
St. Louis, MO 63166-0647

Subject: Notification in Accordance with PR Notice 98-10  
Vesta-Syde Interim Instrument Decontamination Solution  
EPA Registration No. 1043-114  
Application Date: November 5, 2009  
Receipt Date: November 9, 2009

Dear Mr. Sarli:

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

**Proposed Notification**

Notification of additional influenza A virus per PR Notice 95-2

**General Comments**

Based on a review of the material submitted, the following comments apply:

The notification is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6427 or email address at: [Carlisle.shaRon@epa.gov](mailto:Carlisle.shaRon@epa.gov) or Renae Whitaker by telephone at (703) 308-7003 or email at [whitaker.renae@epa.gov](mailto:whitaker.renae@epa.gov) during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in cursive script that reads "ShaRon Carlisle".

ShaRon Carlisle  
(Acting) Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

United States <b>EPA</b> Environmental Protection Agency Washington, DC 20460	Registration Amendment Other (Notification) <input checked="" type="checkbox"/>	OPP Identifier Number
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**Application for Pesticide - Section I**

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

**Section - II**

Amendment - Explain Below Resubmission in response to Agency letter dated _____	Final printed labels in response to Agency letter dated _____ "MeToo" Application
<input checked="" type="checkbox"/> Notification - Explain below	Other - Explain below

**Notification of Additional Influenza A virus claim per PR Notice 95-2**


This notification is consistent with the provisions of PR Notice 95-2 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 18U.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 95-2 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**

<b>1. Material This Product will be Packaged In:</b>				<b>2. Type of Container</b>	
Child-Resistant Packaging Yes* <input checked="" type="checkbox"/> No	Unit Packaging Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging Yes <input type="checkbox"/> No		Metal	
*Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	<input checked="" type="checkbox"/> Other (Specify) foil pouch
<b>3. Location of Net Contents Information</b> <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		<b>4. Size(s) Retail Container</b> 2 fl. oz.		<b>5. Location of Label Directions</b> <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
<b>6. Manner in Which Label is Affixed to Product</b>			<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		

**Section - IV**

<b>1. Contact Point</b> (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Michael G. Sarli	Title Lead Regulatory Specialist	Telephone No. (Include Area Code) 314-290-4704
<b>Certification</b> 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.		<b>6. Date Application Received</b>  (Stamped)

2. Signature 	3. Title Lead Regulatory Specialist	
4. Typed Name Michael G. Sarli	5. Date 11/05/09	

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STERIS®



November 5, 2009

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
Regulatory Management Branch 1  
Antimicrobials Division (7510C)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501  
Attn: ShaRon Carlisle, PM #34

Re: Notification for Vesta-Syde Interim Instrument Decontamination Solution (EPA Reg. No. 1043-114)  
Addition of H1N1 Influenza Virus in Compliance with PR Notice 95-2

Dear Ms. Carlisle:

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

- Application for Pesticide (EPA Form 8570-1)
- Labeling (1 copy) - Changes described with comments
- Labeling (1 copy) - "Clean" copy

The language related to the H1N1 Influenza A virus is drawn verbatim from the "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)" EPA publication.

If you have any questions I can be reached at 314-290-4704 or at [mike\\_sarli@steris.com](mailto:mike_sarli@steris.com).

Sincerely,

Michael G. Sarli  
Lead Regulatory Specialist  
STERIS Corporation

Enclosures

# VESTA-SYDE®

## ENZYME PRESOAK

### FOR SURGICAL INSTRUMENTS AND APPARATUS

**Active Ingredients:**

Bacterial Protease .....0.20%

**Inert Ingredients**..... 99.80%

Total .....100.00%

CA.Reg. No. 1043-50001

**SEE BACK PANEL FOR USE INSTRUCTIONS AND ADDITIONAL PRECAUTIONS****KEEP OUT OF REACH OF CHILDREN**

### DANGER

FIRST AID	
If inhaled	<ul style="list-style-type: none"> <li>•Move person to fresh air.</li> <li>•If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>•Call a poison control center or doctor for further treatment advice.</li> </ul>
If on skin or clothing	<ul style="list-style-type: none"> <li>•Take off contaminated clothing.</li> <li>•Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>•Call a poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul style="list-style-type: none"> <li>•Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.</li> <li>•Call a poison control center or doctor for treatment advice.</li> </ul>
If swallowed	<ul style="list-style-type: none"> <li>•Call poison control center or doctor immediately for treatment advice.</li> <li>•Have person sip a glass of water if able to swallow.</li> <li>•Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>•Do not give anything by mouth to an unconscious person.</li> </ul>
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.	

Patent Number 5,489,531

## STERIS Corporation

7501 Page Avenue  
St. Louis, MO 63133 U.S.A.**NET CONTENTS:**

**NOTIFICATION**  
 Date Reviewed: 12/1/09  
 Reviewed By: J. Whitaker

# VESTA-SYDE®

## ENZYME PRESOAK

### FOR USE WITH VESTA-SYDE INTERIM INSTRUMENT DECONTAMINATION SOLUTION

Vesta-Syde Enzyme Presoak is formulated for use on all surgical instruments and apparatus where blood, protein, and mucous form hard to remove soils or where scrubbing is impractical. This material is formulated for use as the first of two steps for interim instrument decontamination once surgery is completed. Vesta-Syde Enzyme Presoak has no biocidal efficacy, and is formulated for use as a digesting agent in proteinaceous soils. Equipment should be sterilized or disinfected by appropriate methods in separate subsequent steps.

**DIRECTIONS:** Dilute 2 ounces of Vesta-Syde Enzyme Presoak per gallon of water in the dirty instrument catch basin or instrument tray. Allow a minimum of 20 minutes contact time as a presoak for optimum results. After soaking for 20 minutes, add 2 ounces of Vesta-Syde Interim Decontamination Solution and allow an additional 20 minutes for the decontamination step to take place. If ultrasonic cleaning is desired, Vesta-Syde Enzyme Presoak may be used in an ultrasonic cleaning system. As with all ultrasonic cleansing procedures, the ultrasonic system should be covered. Allow a minimum of 20 minutes agitation time when using. Use only in conjunction with Vesta-Syde Interim Instrument Decontamination Solution. Do not add other chemicals. Added chemicals may destroy the effectiveness of this product.

### PRECAUTIONARY STATEMENT

**DANGER:** Corrosive. Causes eye and skin damage. Wear goggles or face shield and rubber gloves when handling. Do not get in eyes, on skin, or clothing. Remove contaminated clothing; rinse and launder immediately. Clean up spills immediately. Wash hands thoroughly after use. Keep containers closed when not in use. Keep out of reach of children.

**STORAGE AND DISPOSAL:** Store in a cool dry place. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

Best if used before date on the pouch.

**FOR INSTITUTIONAL USE ONLY.  
NOT FOR HOME USE.**

DRAFT 11/05/09

# 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 ONLY

**Active Ingredients:**

o-phenylphenol.....9.09%  
p-tertiary amyphenol.....7.66%  
**Inert Ingredients.....83.25%**  
Total .....100.00%

### KEEP OUT OF REACH OF CHILDREN DANGER

FIRST AID	
If inhaled	<ul style="list-style-type: none"> <li>•Move person to fresh air.</li> <li>•If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>•Call a poison control center or doctor for further treatment advice.</li> </ul>
If on skin or clothing	<ul style="list-style-type: none"> <li>•Take off contaminated clothing.</li> <li>•Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>•Call a poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul style="list-style-type: none"> <li>•Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.</li> <li>•Call a poison control center or doctor for treatment advice.</li> </ul>
If swallowed	<ul style="list-style-type: none"> <li>•Call poison control center or doctor immediately for treatment advice.</li> <li>•Have person sip a glass of water if able to swallow.</li> <li>•Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>•Do not give anything by mouth to an unconscious person.</li> </ul>
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 eye damage or skin burns. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing spray mist. Wear goggles or face shield (safety glasses), protective clothing and chemical resistant gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before use. **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 device 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 or 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 a cool dry place.  
**PESTICIDE DISPOSAL:** This germicide, its solutions or rinsings from empty containers, should be disposed of in a toilet or service sink served by a sanitary sewer, or in a landfill approved for pesticides.  
**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

## STERIS Corporation

7501 Page Avenue  
St. Louis, MO 63133 U.S.A.

EPA Reg. No. 1043-114      EPA Est. No. 11563-MI-1

#### NET CONTENTS:

PRODUCT MADE IN U.S.A.

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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),<br>Multiply (Methicillin)-Resistant<br>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.

**VIRUCIDAL:** Passes Virucidal Assay (EPA Proposed Method) [Influenza A<sub>2</sub> (Japan), Herpes Simplex Type 2, Vaccinia Virus, and Adenovirus Type 2, Avian Infectious Bronchitis, Avian Laryngotracheitis, Avian Newcastle Disease, and Porcine Pseudorabies], 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 EPA-approved 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.