

1043-87

2/1/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

FEB 1 2010

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

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

Subject: Notification per PR Notice 98-10  
Vesphene IIse  
EPA Registration Number: 1043-87  
Application Date: January 4, 2009  
Receipt Date: November 5, 2009

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:**

- Additional Brand Name of Process **Vesphene 11st Sterile One-Step Cleaner Disinfectant;**
- Label revision per PR Notice 2007-4;
- Add previously approved Interim Instrument Decontamination directions;
- Additional Package Size of 1 fl.oz. and 2fl. oz.. packets.

**General Comments:**

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

Should you have further questions concerning this letter, please contact me at 703-308-6416 or by email at [mcfarlane.jacqueline@epa.gov](mailto:mcfarlane.jacqueline@epa.gov) or Killian Swift by telephone at 703-308-6346 or by email at [swift.killian@epa.gov](mailto:swift.killian@epa.gov). 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 black ink, appearing to read "Jacqueline McFarlane".

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

2098

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

<b>1. Company/Product Number</b> 1043-87	<b>2. EPA Product Manager</b> ShaRon Carlisle	<b>3. Proposed Classification</b>
<b>4. Company/Product (Name)</b> Vesphene IIse	<b>PM # 34</b>	<input checked="" type="checkbox"/> <b>None Restricted</b>
<b>5. Name and Address of Applicant (include Zip Code)</b> STERIS Corp. P.O. Box 147 St. Louis, MO 63166-0647  Check if this is a new address <input type="checkbox"/>	<b>6. Expedited Review.</b> 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**

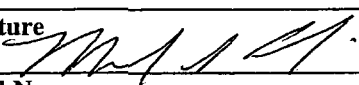
Amendment - Explain Below Resubmission in response to Agency letter dated _____	Final printed labels in response to Agency letter dated _____ "MeToo" Application
<input checked="" type="checkbox"/> Notification - Explain below	Other - Explain below

**Explanation: Notification of reinstatement of label directions for Interim Instrument Decontamination, additional package sizes and corresponding container disposal language as per PR Notice 2007-4 and additional brand name. 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**

<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 checked="" type="checkbox"/> No		Metal	
*Certification must be submitted	If "Yes" Unit Packaging wgt. container	No. per	If "Yes" Package wgt	Paper	
			No. per container	<input checked="" type="checkbox"/> Other (Specify) <u>foil pouch</u>	
<b>3. Location of Net Contents Information</b> <input checked="" type="checkbox"/> Label Container		<b>4. Size(s) Retail Container</b> 1 fl. oz., 2 fl. oz., 1 gal., 5 gal. & 55 gal.		<b>5. Location of Label Directions</b> <input checked="" type="checkbox"/> On Label On Labeling accompanying product	
<b>6. Manner in Which Label is Affixed to Product</b>		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued Stenciled		Other _____	

**Section - IV**

<b>1. Contact Point</b> (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
<b>Name</b> Michael G. Sarli	<b>Title</b> Lead Regulatory Specialist	<b>Telephone No. (Include Area Code)</b> 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>5. Date Application Received (Stamped)</b>
<b>2. Signature</b> 	<b>3. Title</b> Lead Regulatory Specialist	
<b>4. Typed Name</b> Michael G. Sarli	<b>5. Date</b> 1/05/09	

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STERIS®

3098



January 4, 2010

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 Vesphene Ilse (EPA Reg. No. 1043-87)  
Reinstatement of Interim Instrument Decontamination Language  
Additional Package Size of 1 fl. oz. and 2 fl. oz. Packets  
Revision of Container Disposal Language in Compliance with PR Notice 2007-4 for  
Packets  
Additional Brand Name of Process Vesphene Ilst Sterile One-Step Cleaner Disinfectant

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

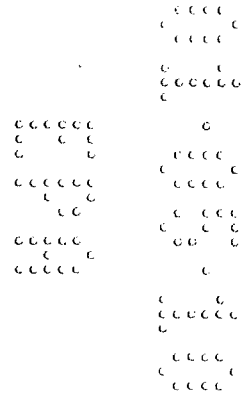
The label has also been revised to add the previously approved Interim Instrument Decontamination directions and Container Disposal statement language for the packets in compliance with PR Notice 9007-4.

We also notify the additional brand name of Process Vesphene Ilst Sterile One-Step Cleaner Disinfectant.

If you have any questions I can be reached at 314-290-4704 or at mike\_sarli@steris.com.

Sincerely,

Michael G. Sarli  
Lead Regulatory Specialist  
STERIS Corporation



Enclosures

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**VESPHENE® IIse**  
**ONE-STEP GERMICIDAL DETERGENT**  
EPA REG. NO. 1043-87      EPA Est. No. 1043-MO-2

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY

Germicide Fungicide Virucide\* Tuberculocide Deodorizer Cleaner Detergent

**Active Ingredients:**

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

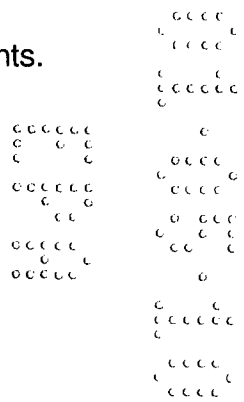
FIRST AID	
If inhaled	<ul style="list-style-type: none"> <li>•Move person to fresh air.</li> <li>•If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>•Call a poison control center or doctor for further treatment advice.</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>
HOT LINE 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.	

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**

See side panel for additional precautionary statements.

**NOTIFICATION**  
Date Reviewed: 2/1/10  
Reviewed By: [Signature]

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



STERILE UNLESS PACKAGING IS COMPROMISED

5098

**PRECAUTIONARY STATEMENT**

**HAZARD TO HUMANS AND DOMESTIC ANIMALS:** Corrosive; Causes eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed.

**(For 5 gal. or larger containers) ENVIRONMENTAL HAZARD STATEMENT:** 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 represents a germicidal detergent system that is both research-developed and state of the art technology. It is effective in hard water and in the presence of serum. It has been formulated as a concentrate to clean, disinfect and deodorize simultaneously. Use this product for easy cleaning and disinfecting of all washable hard, non-porous environmental surfaces such as floors, walls, woodwork, bathroom fixtures, equipment and furniture. It may be used for cleaning and disinfecting chrome, stainless steel, other metal surfaces, porcelain, glass, tile, washable painted or varnished surfaces, as well as resilient vinyl, asphalt, linoleum, terrazzo or other combination type floors. This product is not for use in the neonatal (newborn) units in hospitals, specifically isolates and other infant contact surfaces.

This germicidal detergent is intended for use in institutions such as hospitals and nursing homes, industrial plants, medical and dental offices, pharmaceutical plants, veterinary clinics and other indoor areas where disinfection, cleaning and deodorizing are a necessity.

**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 semicritical medical devices prior to sterilization or high level disinfection.**

**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.

**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
- Candida albicans, Clinical Isolate
- Candida parapsilosis, Clinical Isolate
- Citrobacter freundii, ATCC 8090
- Enterobacter aerogenes, ATCC 13048
- Enterobacter cloacae, ATCC 23355
- Escherichia coli, ATCC 25922
- Klebsiella pneumoniae, ATCC 13883
- Staphylococcus aureus, (MRSA),  
Multiply (Methicillin)-Resistant  
Clinical Isolate
- Proteus mirabilis, Clinical Isolate

- Proteus vulgaris, ATCC 13315
- Pseudomonas aeruginosa, ATCC 27853
- Pseudomonas cepacia, ATCC 25416
- Salmonella typhi, ATCC 6539
- Salmonella typhimurium, ATCC 14028
- Serratia marcescens, ATCC 8100
- Shigella flexneri, ATCC 12022
- Shigella sonnei, ATCC 25931
- Staphylococcus aureus, ATCC 25923
- Staphylococcus epidermidis, ATCC 12228
- Streptococcus faecalis, ATCC 19433
- Streptococcus pyogenes, ATCC 19615

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Vesphene II se 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 10-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.

**.DIRECTIONS FOR USE**

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

**CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES:** Add 1 fl. oz. (30 cc) to each measured gallon of water used (or Add 2 fl. oz. (59.1 mL) to two gallons of pre-measured water used). Always add this product to pre-measured water. Thoroughly mix solution until uniform. Apply solution with a cloth, sponge, mop or brush using normal cleaning methods. Allow treated surfaces to soak for 10 minutes. Then remove excess solution with a wrung-out applicator. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution daily or when it becomes dirty and replace with a fresh solution. A properly prepared solution of Vesphene IIse intended for use as a hard surface disinfectant has a shelf life of 14 days (use life) when stored in a closed container such as a spray bottle. This is a complete product. Do not add other chemicals. If frozen, thaw and re-mix. Use only as directed.

**(For measured dose bottle) CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES:** To make a one gallon (1:128) solution, loosen cap from dispensing chamber. Gently squeeze bottle to fill measuring chamber to the 1 fluid ounce line (30 cc.). Remove cap from the dispensing chamber. Pour measured product (concentrate) from the chamber into one gallon premeasured cold water. Apply solution with a cloth, sponge, mop, brush or from spray bottle using normal cleaning methods. Treated surfaces should remain wet for 10 minutes. Then remove excess solution with a wrung-out applicator. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution daily or when it becomes dirty and replace with a fresh solution. A properly prepared solution of Vesphene IIse intended for use as a hard surface disinfectant has a shelf life of 14 days (use life) when stored in a closed container such as a spray bottle. This is a complete product. Do not add other chemicals. If frozen, thaw and re-mix. Use only as directed.

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**SOLUTION TABLE FOR CONCENTRATE**

Water	1 Gallon	**2 gallons	5 Gallons
Concentrate	1 fl. oz.	**2 fl. oz.	5 fl. oz.

(\*\* For 2 oz. Foil Packet)

**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 use-solution (1 ounce per 1 gallon). Prepare and apply solution as directed in paragraph above.

**Contact Time:** While the HIV-1 virus is inactivated in 1 minute, use a 10-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.

**For Interim Instrument Decontamination prior to Terminal Cleaning and Sterilization of Surgical Instruments and Apparatus:** The removal of heavy soils and the cleaning of all surfaces prior to application of this product is required. All instruments and devices must be thoroughly cleaned to remove excess organic debris, rinsed and then rough dried before immersion. Clean and rinse the lumens of hollow instruments before filling with solution. After cleaning, immerse articles and wet all surfaces thoroughly in a 1:128 solution for 10 minutes. Rinse and dry. Not recommended for prolonged storage of instruments. Avoid splashing and cover, where possible, when transporting soiled instruments. Prepare a new solution daily or when solution turns cloudy or dirty for decontaminating pre-cleaned items.

**STORAGE AND DISPOSAL**

**PROHIBITIONS:** Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

**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:**

(For Packet:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

(For ≤5 gal:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. 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. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. 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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

