

1043-87

10/11/2000

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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OCT 11 2000

Mr. Michael G. Sarli
Regulatory Specialist
STERIS Corp.
P.O. Box 147
St. Louis, MO 63166-0147

Dear Mr. Sarli:

Subject: Efficacy Review 14 Days Holding Period
 for Vesphene II SE
 EPA Registration Number 1043-87
 Your Application Dated April 14, 2000

The submitted confirmatory efficacy data (MRID = 4509989-01) developed by the AOAC Use-Dilution Tests Methods is acceptable to support the subject product 14 day shelf life effectiveness at a dilution of 1:128 in the presence of 5% sterile horse and 400 ppm of synthetic hard water in 10 minutes at 20° C when surfaces are thoroughly wetted by the solution and allowed to remain wet for 10 minutes.

The product effectiveness (14 day shelf life) was demonstrated against Staphylococcus aureus ATCC 6538, Salmonella choleraesuis ATCC 10708, and Pseudomonas aeruginosa ATCC 15442 under the test conditions indicated above.

The labeling referred to above, submitted in connection with registration under Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable for the with the following comments:

- 1. Under the directions for use for the 14 day shelf life product, please clarify or provide additional information to whether the 14 day end solution is as effective in a dark container or does it matter whether the end use solution stored in a clear glass storage bottle.

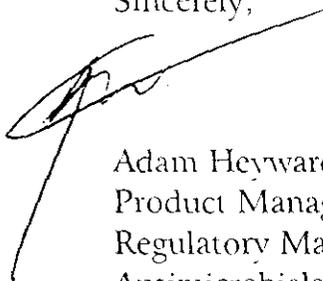
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2. On the middle right panel and at the end of the statement " This product is not to be used as a terminal sterilant..." add the following sentence: This product may be used to preclean or decontaminate critical or semicritical medical devices prior to sterilization or high level disinfection..".
 3. Revise the "First Aid Statement" so that it is in compliance with PR Notice 2000.03. As per the EPA Acute toxicity review dated August 15, 1985, this product is a tox category III for the acute oral exposure route. Therefore, the First Aid Statement must include instructions for acute oral route of exposure. See PR Notice 2000.03 for appropriate wording and label display.
 4. Only be one First Aid Statement paragraph on the label is required. Therefore you must delete the second First Aid Statement paragraph. See PR Notice 2000.03 the appropriate location on the label.

Submit three (3) copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for you records.

If you have questions concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

PRECAUTIONARY STATEMENTS

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.

STATEMENT OF PRACTICAL TREATMENT: In case of eye contact, immediately flush eyes with water for 15 minutes and get prompt medical attention. For skin contact, flush thoroughly with water. Remove and wash contaminated clothing before reuse. If swallowed, promptly drink a large quantity of water. Avoid alcohol. Do not induce vomiting. Call physician immediately. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

(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.

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. 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 wring-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 Vespene 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 wring-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 Vespene 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.

SOLUTION TABLE FOR CONCENTRATE

Water	1 Gallon	5 Gallons
Concentrate	1 fl. oz.	5 fl. oz.

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 Inanimate Instrument Decontamination prior to Thermal 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.

VESPHENE® IIse

ONE-STEP IN THE PRESENCE OF SERUM GERMICIDAL DETERGENT

EPA REG. NO. 1043-87
EPA Est. No. 1043-MO-1

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%

KEEP OUT OF REACH OF CHILDREN
DANGER

STATEMENT OF PRACTICAL TREATMENT

In case of eye contact, flush with water for 15 minutes. Get prompt medical attention. For skin contact, flush with water immediately. See side panel for additional precautionary statements.

NET CONTENTS:

(Logo) **STERIS Corporation**

3035 Manchester Avenue
St. Louis, MO 63110 U.S.A.

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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 pesticide, its solutions or mixings, from empty containers should be disposed of in a toilet or sewer and served by a sanitary sewer, or in a landfill approved for pesticides.

CONTAINER DISPOSAL: Triple rinse and deposit in a waste container for the incineration or in a landfill approved for pesticide containers.

GENERAL: Consult Federal, State, or Local disposal authorities for approved alternative procedures such as limited open burning.

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, schools, 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.

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.

<i>Acinetobacter calcoaceticus</i> , ATCC 19606	<i>Proteus vulgaris</i> , ATCC 13315
<i>Candida albicans</i> , Clinical Isolate	<i>Pseudomonas aeruginosa</i> , ATCC 27853
<i>Candida parapsilosis</i> , Clinical Isolate	<i>Pseudomonas cepacia</i> , ATCC 25416
<i>Citrobacter freundii</i> , ATCC 8090	<i>Salmonella typhi</i> , ATCC 6309
<i>Enterobacter aerogenes</i> , ATCC 13048	<i>Salmonella typhimurium</i> , ATCC 14028
<i>Enterobacter cloacae</i> , ATCC 23355	<i>Serratia marcescens</i> , ATCC 8100
<i>Escherichia coli</i> , ATCC 25922	<i>Shigella flexneri</i> , ATCC 12922
<i>Klebsiella pneumoniae</i> , ATCC 13883	<i>Shigella sonnei</i> , ATCC 24931
<i>Staphylococcus aureus</i> , (MRSA), Multiply (Methicillin)-Resistant Clinical Isolate	<i>Staphylococcus aureus</i> , ATCC 25923
<i>Proteus mirabilis</i> , Clinical Isolate	<i>Staphylococcus epidermidis</i> , ATCC 12228
	<i>Streptococcus faecalis</i> , ATCC 19433
	<i>Streptococcus pyogenes</i> , ATCC 19615

Vespene IIse 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 A₁ (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.

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