



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 19, 1997

Mr. Michael G. Sarli, Regulatory Specialist
Steris Corporation
Post Office Box 147
St. Louis, MO 63166

Dear Mr. Sarli:

Subject: Proposed Minor Label Change
"Vesphene IIse"
(EPA Reg. No. 1043-87)
Amendment dated July 22, 1997

The proposed label revision referred to above, submitted in connection with registration under the amended Federal Insecticide, Fungicide and Rodenticide Act is acceptable with comments. Our comments are as follows:

- Revise "As solution becomes dirty, discard and replace with a fresh one.", to read as follows: Daily discard solution or when it becomes dirty and replace with a fresh one.

If any revision was made to the subject product label to alter it from the approved label, dated February 20, 1997, other than in the "Directions For Use" section, as specified in the amendment submission dated July 22, 1997, the product registration will become subject to cancellation in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act section 6(e).

If you have any question or concerns, please call me at (703) 308-6230, or Killian Swift of my staff at (703) 308-6346.

Sincerely yours,

A handwritten signature in cursive script that reads "Portia M. Jenkins".

Portia M. Jenkins,
Acting Product Manager 34
Regulatory Mgmt. II
Antimicrobial Div. (7510W)

Enclosure

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 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.

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-PORUS 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. As solution becomes dirty, discard and replace with a fresh one. This is a complete product. Do not add other chemicals. If frozen, thaw and remix. Use only as directed.

CLEANING AND DISINFECTING WASHABLE, HARD, NON-PORUS 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. This is a complete product. Do not add other chemicals. If frozen, thaw and remix. 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 OF 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.

STORAGE AND DISPOSAL

PROHIBITION: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not use empty container.

PESTICIDE DISPOSAL: This germicide, its solution or its residues 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: Triple rinse and deposit in a waste container for 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.

Calgon Vestal

VESPHENE® II se
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 amylphenol..... 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.

ACCEPTED
with COMMENTS
EPA Letter Dated:
8-19-97

NET CONTENTS: 1 Gal.
55 Gal.

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
1043-87

(Logo) **STERIS Corporation**
CALGON VESTAL Division
5035 Manchester Avenue
St. Louis, MO 63110 U.S.A.

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 doors, 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 6539
<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 12022
<i>Klebsiella pneumoniae</i> , ATCC 13883	<i>Shigella sonnei</i> , ATCC 25931
<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

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, (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. Classified by Underwriter's Laboratories, Inc. as to electrical conductivity when used on conductive floors and spontaneous heating. Vesphene II se - For use with listed electrical conducted flooring of the vinyl type. 942P.

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