

PM 34

1043-115

8-28-98

1043

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 28 1998

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

Dear Mr. Sarli:

Subject: Addition of directions for interim instrument decontamination
Steris Process Vesphene Iise
EPA Registration No. 1043-115
Amendment application of July 10, 1998

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(a)(7)(A), is acceptable provided that you:

1. Submit and/or cite all data or other material required for registration/registration of your product under FIFRA sec. 3(c)(5) or FIFRA sec. 4 when the Agency requires all registrants of similar product to submit such data.
2. Make the labeling change listed below before you release the product for shipment:

The following statement must be added to the labeling:

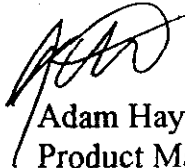
“This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does 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.”

3. Submit two copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

CONCURRENCES							
SYMBOL	7510W						
SURNAME	Denkin						
DATE	8-28-98						

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Sincerely yours,



Adam Hayward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (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. Rinse if swallowed.

STATEMENT OF PRACTICAL TREATMENTS: 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 a 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 STATEMENTS: (For containers 5 gallons and larger) 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 Pollution 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 O. oz. (90 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. Thoroughly wet all surfaces to be cleaned. Treated surfaces should remain wet for 10 minutes. Remove excess solution with a wet-cloth applicator. Remove gross dirt mechanically by sweeping before cleaning begins. Discard solution daily or when it becomes dirty and replace with a fresh solution. This is a concentrate product. Do not add other chemicals. If frozen, thaw and re-test. Use only as directed.

SOLUTION TABLE FOR CONCENTRATE

Water	1 gallon	**1 gallons	5 gallons
Concentrate	1 fl. oz.	**2 fl. oz.	5 fl. oz.

(* * Per 2 oz. Gall 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, gown, mask or eye covering.

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: Dispose of blood and other body fluids should be collected and disposed of according to local regulations for infectious disposal.

For Infective 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, dried and then soaked/delid before immersion. Clean and flush the lumens of hollow instruments before filling with solution. After cleaning, immerse needles 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.

PROCESS VESPHENE® 11st
STERILE

ONE-STEP IN THE PRESENCE OF SERUM
GERMICIDAL DETERGENT

EPA REG. NO. 1043-115

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY

Germicide • Fungicide • Virucide • Tuberculocide
Deodorizer • Cleaner • Detergent

Active Ingredients

o-phenylphenol.....	9.09%
p-tertary 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.

STERILE UNLESS PACKAGING IS COMPROMISED

ACCEPTED
with COMMENTS
in EPA Letter Dated 11/11/88

AUG 28 1998

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide.

registered under EPA Reg. No.

(LOGO) STERIS Corporation

5035 Manchester Avenue
St. Louis, MO 63110 U.S.A.

EPA Reg. No. 1043-115-1

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 slurries from empty containers, should be disposed of in a toilet or service sink served by a sanitary sewer, or in a landfill approved for pesticide.

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

RECYCLING: Consult local, state or federal 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, which 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 germicidal detergent is intended for use on washable, hard, non-porous environmental surfaces such as floors, walls, counters, locks, units and other equipment in clean rooms, pharmaceutical plants and in other areas where anti-bacterial control measures are necessary.

GERMICIDAL: Passes A.O.A.C. Germicidal Use-Dilution Method (S. aureus, S. choleraesuis, P. 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 19625	<i>Protista vulgaris</i> , ATCC 13313
<i>Candida albicans</i> , Clinical Isolate	<i>Pseudomonas aeruginosa</i> , ATCC 27933
<i>Candida parapsilosis</i> , Clinical Isolate	<i>Salmonella typhi</i> , ATCC 4339
<i>Citrobacter detroitii</i> , ATCC 4939	<i>Salmonella typhimurium</i> , ATCC 14028
<i>Enterobacter aerogenes</i> , ATCC 13048	<i>Serratia marcescens</i> , ATCC 8100
<i>Enterobacter cloacae</i> , ATCC 23333	<i>Shigella boydii</i> , ATCC 12011
<i>Escherichia coli</i> , ATCC 25922	<i>Shigella sonnei</i> , ATCC 25931
<i>Klebsiella pneumoniae</i> , ATCC 13637	<i>Staphylococcus aureus</i> , ATCC 29923
<i>Multiphyllum (Mycobacterium) fortuitum</i>	<i>Staphylococcus epidermidis</i> , ATCC 12227
<i>Staphylococcus aureus</i> , (MRSA), Clinical Isolate	<i>Stenotrophomonas maltophilia</i> , ATCC 19433
<i>Proton mirabilis</i> , Clinical Isolate	<i>Streptococcus pyogenes</i> , ATCC 19613

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 1, Avian Infectious Bronchitis, Avian Laryngotracheitis, Avian Nephritis 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.

Best AVAILABLE COPY

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