

1043-115

03/30/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 30 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Mike Sarli
STERIS Corporation
PO Box 147
St. Louis, MO 63166-0147

Subject: Vesphene Iist
EPA Registration No.: 1043-115
Amendment Date: January 28, 2011
EPA Receipt Date: January 30, 2011

Dear Mr. Sarli:

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with conditions.

Proposed Amendment

- Adding establishment number and container sizes
- Updating organism nomenclature and precautionary statements

Conditions

Revise the label as follows:

- 1.) Delete the term, "Only," from the phrase, Industrial and Institutional Only.
- 2.) Qualify surfaces as hard nonporous by stating "glazed" porcelain, "glazed" tiles, and "finished" woodwork.
- 3.) Delete the phrase, "EPA Proposed Method" and "EPA Approved" phrases from the Virucidal claims. You may indicate "AOAC Use Dilution Method."
- 4.) The nomenclature for Influenza A2, Herpes Simplex Type 2, Avian Laryngotracheitis, Avian Newcastle Disease, and Porcine Pseudorabies is incomplete. You must add the term, "virus" to the name of each organism.

CONCURRENCES

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5.) The "Precautionary Statements" must be updated to be in agreement with the Label Review Manual (<http://www.epa.gov/oppfead1/labeling/lrm/>) by stating:

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed, inhaled, or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eye wear (goggles or faceshield), protective clothing, or rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, or using the toilet.

6.) According to PR Notice 2001-1, the First Aid statements must be arranged so that the most severe routes of exposure, as demonstrated by the toxicity classification, are listed first. Therefore, rearrange the statements to reflect: "If in Eyes, If on Skin, If Swallowed, and If Inhaled."

7.) Revise the "Personal Protection" statement under the HIV directions by deleting the term, "or" and state "and." The personal protection items that are used to clean blood and body fluids are not optional.

8.) The "Storage and Disposal" statements are not in compliance with PR Notice 83-3 and PR Notice 2007-4. Revise them to reflect the following:

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in original container in areas not accessible to persons unfamiliar with its use.

Pesticide Disposal: Pesticide wastes may be acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Nonrefillable container. Do not refill or reuse this container. Offer for recycling if available. *If not, puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities.* The rest of the statements on the label are acceptable.

General Comments

A stamped copy of the accepted label with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

If you have further questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Glen McLeod by telephone at (703) 347-0181 or by email at mcleod.glen@epa.gov. When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

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Sincerely,



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

Enclosure: Stamped Label

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STERIS® Process Vesphene® II ST
The Technology of Clean® Steris One Step Cleaner/Disinfectant

Formular Number: 6881-08 Net Contents: 3.78 Liters (1 Gal.)

STERILE UNLESS PACKAGING IS COMPROMISED
Germicide • Fungicide • Virucide*
Tuberculocide • Deodorizer • Cleaner • Detergent

Active Ingredients:
o-phenylphenol..... 9.09%
p-tertiary amylphenol..... 7.56%
Isosr ingredients..... 83.25%
Total..... 100.90%

EPA REG. No. 1043-115 EPA Est. No. 1043-MD-2
EPA Est. No. 11563-MJ-1
KEEP OUT OF REACH OF CHILDREN

DANGER

FOR INDUSTRIAL AND INSTITUTIONAL USE

See side panel for additional precautionary statements

STERIS Corporation
7501 Page Avenue
St. Louis, MO 63133 • USA
800-548-4873
www.steris.com

181.02.
291.02.

FIRST AID	
If inhaled	• Move person to fresh air • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible • Call a poison control center or doctor for further treatment advice
If on skin or clothing	• Take off contaminated clothing • Rinse skin immediately with plenty of water for 15-20 minutes • Call a poison control center or doctor for treatment advice
If in eyes	• Hold eye open and rinse slowly and gently with water for 15-20 minutes • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye • Call a poison control center or doctor for treatment advice
If swallowed	• Call a poison control center or doctor immediately for treatment advice • Have person sip a glass of water if able to swallow • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person
NOT TO BE USED: Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
PRECAUTIONS: Possible mutual damage may contraindicate the use of plastic bags.	

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, or terrazzo type floors.

This germicidal detergent is intended for use on washable, hard, non-porous environmental surfaces such as floors, walls, counters, tools, carts and other equipment in clean rooms, and pharmaceutical plants.

This product is not to be used as a terminal sterilant/edge-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 pre-clean 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. enterica*, *Pa. 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>Aeromonas hydrophila</i> , ATCC 19606	<i>Staphylococcus aureus</i> (USA)	<i>Serratia marcescens</i> , ATCC 6100
<i>Candida albicans</i> , Clinical Isolates	Mutiple (Munich) Resistant	<i>Shigella flexneri</i> , ATCC 12022
<i>Candida parapsilosis</i> , Clinical Isolates	Clinical Isolates	<i>Shigella sonnei</i> , ATCC 25921
<i>Clostridium botulinum</i> , ATCC 8020	<i>Proteus mirabilis</i> , Clinical Isolates	<i>Staphylococcus aureus</i> , ATCC 29622
<i>Enterobacter aerogenes</i> , ATCC 13048	<i>Proteus vulgaris</i> , ATCC 13135	<i>Staphylococcus epidermidis</i> , ATCC 12228
<i>Enterobacter cloacae</i> , ATCC 27053	<i>Providencia aerogenes</i> , ATCC 27853	<i>Staphylococcus lentiginosus</i> , ATCC 19430
<i>Escherichia coli</i> , ATCC 25922	<i>Salmonella typhi</i> , ATCC 10738	<i>Streptococcus pyogenes</i> , ATCC 19615
<i>Klebsiella pneumoniae</i> , ATCC 13288	<i>Salmonella typhisicca</i> , ATCC 14028	

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.

***VRUCIDAL:** Passes Virucidal Assay (Influenza A₂ (Japan), Herpes Simplex Type 2, Vaccinia Virus, and Adenovirus Type 2, Avian Infectious Bronchitis, Avian Laryngotracheitis, Avian Newcastle Disease, and Porcine Pseudotuberculosis), 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.

When tested by an **ATCC** 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.

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.

PRECAUTIONARY STATEMENTS
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 dirt 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 Process Vesphene that is intended for use as a hard surface disinfectant has a shelf life of 14 days (use by) 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, 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

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: 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 3/4 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. General: Consult Federal, State, or Local disposal authorities for approved alternative procedures, such as limited open burning.

6881-061H(1210) 80992 Product Mar

ACCEPTED
with COMMENTS
EPA Letter Dated:
MAR 3 0 2011

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
10413-115

h/t