



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

MAR 3 0 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.

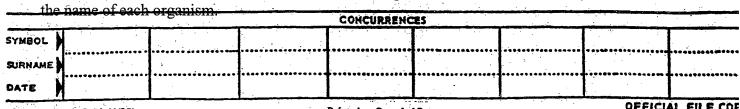
Proposed Amendment

- 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



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. Washthoroughly 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 incompliance 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 in accessible to persons unfamiliar with its

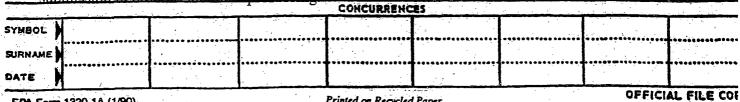
Pesticide Disposal: Pesticide wastes may be acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or 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



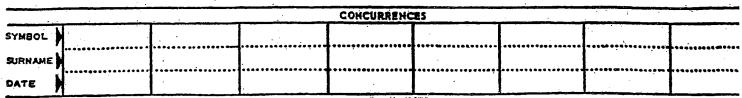
Sincerely,

Jacqueline Campbell-McFarlane (Product Manager (34)

Regulatory Management Branch II Antimicrobials Division (7510P)

Enclosure:

Stamped Label /





Process Vesphene® IIst

he fechnology of Occur. Sternle Girle Stell Cleaner Grainfection

6861-08

\$1.02. 281.02 3.78 Liters (1 Gal.)

STERILE UNLESS PACKABING IS COMPROMISED Germicide • Funnicide • Virucide • Tuberculocide • Decdorizer • Cleaner • Detergent

Active Ingredients: o-phsmylphsnot 9.09% p-tertiary amylphenot 7.66%

EPA EST. NO. 1043-115 EPA EST. NO. 1043-NO-2 EPA EST. NO. 11563-MT-1 KEEP OUT OF REACH OF CHILDREN DANGER

FOR INDUSTRIAL AND INSTITUTIONAL USE

See side panel for edditional precautionary statements

www.steris.com

STERIS Corporation 7501 Page Avenue St. Louis, MO 63133 = USA 800-548-4873

HRST AID Move person to Each ax
 F person to not benezing, call 811 or an archanous, then give efficiel responsion protected by by count-to-counts. If possible had a possible control unique or factor for Each archanol control unique or factor for Each archanol control unique or factor. Lide of contentand detains Plans the immediately with planty of wide in 15-20 minutes. Hidd spe open and rists story and gartly with voter for 15-20 entered from the control and the control and the least 5 entered, then control the least 5 entered, then control the the 5 entered from the control the control that the specific specif Cad a polition control conten or discline for tractiment whites. Call possess control center or discorr Old personn control quarter per discours immediately for treatment activities.
 Varies person tip is glace of vector il activi to mediate.
 Do met relace vecnolog emisso lodd to do so by the potrom control control or doctor.
 Do met glace implicit by mouth to an unconcellate person.

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MOTE 10 PHOSPERM

This product represents a germicidal detergent system that is both research-developed and state of TUBERCULQCOAL: Passes A.O.A.C. Tuberculocidal Test (Alycobacterium huberculosis, the art technology, It is effective in hard water and in the presence of serum. It has been formulated var. bowls) when deuted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 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 fodures, 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 resident 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 obarmaceutical niants.

This product is not to be used as a terminal sterilar/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 stedie areas of the body, or (2) contacts intest nuceous membranes but which does not ordinarily genetrate the blood barrier or otherwise enter normally startle areas of the body. This greatest may be used to pre-clean or deconteminate critical or semicritical medical devices prior to sterification or high level distintection.

GERANCIDAL: Passes A.O.A.C. Germicidal Use-Dilution Method (S. aureus, S. enterica, Ps. aerughrosa) when diluted with 400 ppm AOAC, hard water to make a 1:128 (1 ounce per gation) solution, in the presence of 5% organic soli (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:

Acces toward convenience ATCC 19606 Condition of the Condit Francischer europenes, ATCC 13048 Francischer chance, ATCC 23355

CONSCI BOXES
Probes Ministra, Cisclad bodes
Protes velgers, AFCC 12015
Petadoricas seruptosa, AFCC 77653
Salmoneta hypit, AFCC 6639

Servatta manuscers, ATCC 8100 Shipsia Decent, ATCC 12022 Shipsia scend, ATCC 25931 Schildrennon month, ATCC COST CONTROL AT CC 25923 Staphylacoccus midwinides, ATCC 12221 Streptococcus temple, ATCC 19433

FUNGICIDAL: Passes A.O.A.C. Fungicidal Test (T. memagrophytes) 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

1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C .

"VIRUCIDAL: Passes Virucidal Assay ((Influenza Az (Japan) Harpes Simplex Type 2, Vaccinia Virus, and Adenovirus Type 2, Avian Infectious Bronchilis Avian Laryngotrachetts, Avian Newcastle Disease, and Porcine Pseudorables], when distred 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 Dilution Method, the HIV-1 (AIDS) virus, with added To the organic soil (serum), was completely inactivated by a 1128 (1 ounce par 1 gation) 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 a be sufficient for other organisms. Use a 10-minute contact time for disinfection equinst all of the organisms claimed. Kills Pandemic 2009 H1N1 Influenza A virus formerly called swine flu.

ODOR CONTROL: It eliminates many odors by letting odor-causing bacteria while simultaneously chemically neutralizing their odors and leaving a pleasant francance. PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANGMALS: Corrosive: Causes eve and skin damage. Do not get in eyes, on side, or on clothing. Wear googles or face shield and rubber gloves when handing. Harmful if swallowed.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Clearling and disconfecting washable, hard, non-porcus surfaces: Add 1 ft. 0z. (30 cc) to each measured getton of water used. Always and 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

sportige, morp, or order lasting informat casting intended, shown treated surfaces to solar for 10 minutes. Then remove excess solution with a wrung-out application. Remove gross fith medicarically by sweeping before desiring begins. Discard solution daily or when it becomes dury and reptace with a fresh solution. A property prepared solution of Processes Vesiphane tall intended for use as a hard surface distinction has a shall the of 14 days (use life) when stored in a closed complete such as a spray bottle. This is a complete product. On not add other chemicals. If frozen, thaw and re-mix. Use only as directed. SOLUTION TARLE FOR CONCENTRATE

1 gallon 5 gasions 1 fl. oz. 5 fl. oz.

ICILS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOLED WITH BLOOD/BODY. FLUIDS in health care settings or other settings in which there is an expected Distilling of of soling 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

SPECIAL DISTRUCTIONS FOR CLEANING AND DECONTAMONATION AGAINST HRI-1 (NUMBAN PROBLEMODEFICIENCY VIRUS OR ARDS VIRUS) OF SURFACES/OBJECTS SOLIED WITH BLOOD/BODY FLUIDS:

Personal prescriber: Wear appropriate barrier protection, such as letex 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. disourpliny desired mini strikeds and opply solution as directed in paragraph above. Contact times: While the HiV-1 virus is inactivated in 1 minute, use a 10-minute contact time for disinfection of all organisms on this table! Infectious materials disposal: Blood and other body fluids should be autoclaved and disposed of according to local regulations for intectious disposal.

STORAGE AND DISPOSAL

dumping is prohibited. Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container. Posticide disposal: This germidde, its solutions or rinsings from empty containers, should be disposed of in a toilet or service. sink served by a santiary sewer, or in a landfill approved for pessicides: Confidence disposal Nonrefitable container. Do not reuse or reful this container. Offer for recycling, if available remains comment. On the research of the was placed in the property of the comment of the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container is 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 Oraln 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 atternative procedures, such as limited open burning.

6861-06HH(1210)

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.

1043-115