



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 24, 2018

Jennifer Pavlovsky
Manager, Regulatory Affairs
STERIS Corporation
PO Box 147
St. Louis, MO 63166-0147

Subject: Label Notification per PRN 98-10 – Notification for Personal Protective Equipment for clarification of labeling policy for antimicrobial pesticides bearing effectiveness against HIV Federal Register Notice 40 CFR Part 162-2/9/1989
Product Name: Vesphene® IIIse Phenolic Disinfectant
EPA Registration Number: 1043-128
Application Date: June 18, 2018
Decision Number: 542389

Dear Ms. Pavlovsky:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, you may contact Srinivas Gowda at 703-308-6354 or via email at gowda.srinivas@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Srinivas Gowda for".

Jacqueline Hardy
Product Manager – Team 34
Regulatory Management Branch II
Antimicrobials Division (7510P)
Enclosure: “Notification” Stamped EPA Label

Vesphene[®] Illse Phenolic Disinfectant

Reorder Number: XXX

Net Contents: XXX

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

[When diluted with soft or hard water (400 ppm CaCO₃) even in the presence of organic soil (5% serum)]

NOTIFICATION

INTENDED FOR INDUSTRIAL AND INSTITUTIONAL USE

1043-128

Active Ingredients:

o-phenylphenol.....6.00%

o-benzyl-p-chlorophenol.....12.75%

Inert Ingredients:81.25%

Total:100.00%

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

07/24/2018

EPA Reg. No. 1043-128 [EPA Est. No. 211-KS-001] [EPA Est. No. 1043-MO-2] [EPA Est. No. 11563-MI-1]

**KEEP OUT OF REACH OF CHILDREN
DANGER**

FIRST AID	
If in eyes	<ul style="list-style-type: none"> •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 on skin or clothing	<ul style="list-style-type: none"> •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 inhaled	<ul style="list-style-type: none"> •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 swallowed	<ul style="list-style-type: none"> •Call 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.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

See [side panel] [back panel] [insert] for additional precautionary statements [and] [or] [directions for use].

STERIS Corporation
7501 Page Ave.
St. Louis, MO 63133 U.S.A.
1-800-548-4873

Product Made in U.S.A.

[Brackets denote optional text.]

06/15/2018

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS:

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Harmful if inhaled. Avoid breathing vapor or spray mist. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear, gloves and clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARD STATEMENT: (*For use on containers 5 gallons and larger*) Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters 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.

Vesphene® IIIse is a germicidal detergent system that is effective in hard or soft water even in the presence of organic soil (5% blood serum). It has been formulated as a concentrate to clean, disinfectant 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 in institutions such as hospitals and nursing homes, industrial plants, 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 blood stream 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.

GERMICIDAL: When tested against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442), it passes the A.O.A.C. Germicidal Use-Dilution Test, the AOAC Fungicidal Activity of Disinfectants Test for *Trichophyton interdigitale* and the Virucidal Hard-Surface Efficacy Test for Influenza A2 Virus when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (one ounce per one gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

BACTERICIDAL: When tested against *Acinetobacter baumannii* (ATCC 19606), *Escherichia coli* (ATCC 25922), *Enterobacter cloacae* (ATCC 13047), *Micrococcus yunnanensis* (ATCC 7468), *Serratia marcescens* (ATCC 14756), *Staphylococcus epidermidis* (ATCC 12228), *Burkholderia cepacia* (ATCC 25416), *Listeria monocytogenes* (ATCC 19111), *Mycoplasma gallisepticum* (ATCC 15302), *Streptococcus pyogenes* (ATCC 19615), it passes the A.O.A.C. Germicidal Use-Dilution Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (one ounce per one gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

FUNGICIDAL: When tested against *Trichophyton interdigitale* (ATCC 9533) and *Candida albicans* (ATCC 10231), it passes the A.O.A.C. Fungicidal Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (one ounce per one gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

TUBERCULOCIDAL: When tested against *Mycobacterium tuberculosis* var. *bovis*, BCG it passes the A.O.A.C. Tuberculocidal Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (one ounce per one gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

* **VIRUCIDAL:** When tested against Influenza A2 Virus (H2N2), A/2/Japan/305/57 (Charles River Laboratories), Adenovirus Type 2, Strain: Adenoid 6 (ATCC VR-846) and Avian Influenza Virus (H9N2), (Strain A/Turkey/Wis/66) (Charles River Laboratories) it passes the Virucidal Assay (EPA Proposed Method) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (one ounce per one gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 20°C.

When tested, the Human Immunodeficiency Virus Type 1 (HIV-1), Strain: III_B with added 5% organic soil (serum), was completely inactivated by a 1:128 (one ounce per one gallon) solution in 400 ppm A.O.A.C. hard water in 10 minutes at 20°C.

ODOR CONTROL: This product eliminates many odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors and leaving a pleasant fragrance. Follow “**CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES**” directions.

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: To make one gallon of solution, pre-measure one gallon of water, remove one fluid ounce (30 cc) of water and replace with one fluid ounce of product (Vesphene IIIse Phenolic Disinfectant). Gently mix until solution is uniform. **NOTE:** Always add this product (concentrate) to pre-measured water. Apply solution with a cloth, sponge, mop, brush or by coarse spray using normal cleaning methods. Allow treated surfaces to remain wet for 10 minutes, then remove excess solution with a wrung-out applicator. A properly prepared solution of this product is intended for use as a hard surface disinfectant. Make daily preparation. But when planning to store preparation up to 35 days, dilute product with deionized water. Before cleaning begins, always sweep or dust mop area to be cleaned thoroughly, removing any gross filth. This is a complete product. Do not add or dilute with other chemicals. If frozen, thaw and re-mix before use. Use only as directed.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in 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 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 Specific barrier protection items to be used when handling items soiled with blood or body fluids are such as disposable latex gloves, gowns, masks and 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 (one ounce per one gallon) Prepare and apply solution as directed in paragraph above.

Contact Time: Allow treated surfaces to remain wet for 10 minutes.

Infectious Materials Disposal: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

[FOR INTERIM 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 applications 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 thoroughly and dry. Not recommended for prolonged storage of instruments. A properly prepared solution of this product is intended for use as a hard surface disinfectant. Prepare a new solution daily or when solution turns cloudy or dirty for decontaminating pre-cleaned items.]

[Brackets denote optional text.]

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Do not store near heat or open flame. If frozen, thaw and remix before use.

PESTICIDE DISPOSAL: Pesticide wastes are 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:

(For Packet:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or dispose in sanitary landfill or by other procedures approved by state and local authorities.

(For ≤5 gal:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or dispose in sanitary landfill or by other procedures approved by state and local authorities. 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 ¼ 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.

(For > 5 gal:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or dispose in sanitary landfill or by other procedures approved by state and local authorities. Clean container promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

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

[Sterile unless packaging is compromised.]

[Brackets denote optional text.]