

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

24 FEB 1994

Calgon Vestal Laboratories
Division of Calgon Corporation
P.O. Box 147
St. Louis, MO 63166

Attn: Michael Ebers

Subject: Vesphene II se
EPA Registration No. 1043-87
Your Submissions of May 25, and November 3, 1993

The amendment requests noted above involving revised labeling text concerning proposed restrictions on the use of the subject product have been reviewed. Please note the following.

1. The proposal for restricting use of this product in neonatal areas in hospitals is acceptable.
2. The proposed label text incorporating the language of the EPA and FDA MOU (Memorandum Of Understanding) concerning areas of restriction for product use is acceptable.
3. The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records. Five copies of the finished labeling must be submitted before you release the product for shipment.
 - a. In the paragraph regarding the language of the FDA/EPA MOU on page 3 of the submitted draft label, revise the first sentence to read: "This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced..."

REFERENCES							
SYMBOL	7505K						
SURNAME	Zanotti						
DATE	24 FEB 1994						

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If you should have any questions about this letter, you may call Robert Travaglini on (703) 305-6909.

Sincerely,



Ruth G. Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

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REGISTERED
with OCSPP/OPDS
in EPA Letter Docket

24 FEB 1994

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

1043-87

VESPHENE II_{se}

ONE-STEP IN THE PRESENCE OF SERUM
GERMICIDAL DETERGENT

EPA REG. NO. 1043-87

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY

Germicide • Fungicide • Virucide*

Tuberculocide • Deodorizer • Cleaner • Detergent

Active ingredients	
Sodium o-phenylphenate	9.65%
Sodium p-tertiary amyphenate	8.34
Inert ingredients	82.01

0027

**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 statement

NET CONTENTS: 1 U.S. GALLON (3.78 liters)



DIVISION OF CALGON CORPORATION
SUBSIDIARY OF MERCK & CO., INC.
St. Louis, Missouri 63133

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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 of water. Avoid alcohol. Do not induce vomiting. Call a physician immediately. **NOTE TO PHYSICIANS:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

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, NONPOROUS SURFACES: Add 1 fl. oz. (30cc) to each measured gallon of water used. Always add this product to premeasured 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, then remove excess solution with a wringing out applicator. Treated surfaces should remain wet for 10 minutes. 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 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, 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 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 collected and disposed of according to local regulations for infectious disposal.

STORAGE AND DISPOSAL

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

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

6461-06D(392)

EPA Est. No. 1043-MO-1

APPROVED
with COMMENTS
by EPA Letter (Date)

24 FEB 1994

1043-87

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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 product is not for use in the neonatal (newborn) units in hospitals, specifically isolettes 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 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 27°C.

- | | | |
|-------------------------------------------------|---------------------------------------------|------------------------------------------------|
| <i>Acinetobacter calcoaceticus</i> , ATCC 19606 | Multiply (Methicillin)-Resistant | <i>Serratia marcescens</i> , ATCC 8100 |
| <i>Candida albicans</i> , Clinical isolate | <i>Staphylococcus aureus</i> (MRSA), | <i>Shigella flexneri</i> , ATCC 12022 |
| <i>Candida parapsilosis</i> , Clinical isolate | Clinical isolate | <i>Shigella sonnei</i> , ATCC 25931 |
| <i>Citrobacter freundii</i> , ATCC 8090 | <i>Proteus mirabilis</i> , Clinical isolate | <i>Staphylococcus aureus</i> , ATCC 25923 |
| <i>Enterobacter aerogenes</i> , ATCC 13048 | <i>Proteus vulgaris</i> , ATCC 13315 | <i>Staphylococcus epidermidis</i> , ATCC 12228 |
| <i>Enterobacter cloacae</i> , ATCC 23355 | <i>Pseudomonas aeruginosa</i> , ATCC 27853 | <i>Streptococcus faecalis</i> , ATCC 19433 |
| <i>Escherichia coli</i> , ATCC 25922 | <i>Salmonella typhi</i> , ATCC 6539 | <i>Streptococcus pyogenes</i> , ATCC 15615 |
| <i>Klebsiella pneumoniae</i> , ATCC 13833 | <i>Salmonella typhimurium</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.

VIRUCIDAL: Passes Virucidal Assay (EPA Proposed Method) [Influenza A₂ (Japan), Herpes simplex Type 2, Vaccinia, 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), 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 54 - For use with listed electrically conducted flooring of the vinyl type, 942P.

APPROVED
with COMMENTS
in EPA Letter Order

24 FEB 1994

Under the Federal Insecticide,
Fungicide, and Herbicide Act as
amended, for the pesticide
registered under EPA Reg. No.

1043-87

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