

MAY 26 1995

Calgon Vestal Laboratories
P.O. Box 147
Saint Louis, MO 63166-0147

Attention: Susie Amberger

Subject: Vesphene II_{se}
EPA Registration Number 1043-87
Your Submission Dated June 23, 1994
EPA Received Date September 12, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add two additional bacteriocidal claims to the product labeling, is acceptable.

The submitted efficacy data are acceptable to support the effectiveness of the product as a disinfectant against Pseudomonas cepacia ATCC 25416 on hard, non-porous surfaces at a 1:28 solution in the presence of 5% organic serum and 400 ppm AOAC hard water for a contact time of 10 minutes at 20 degrees Celsius.

The submitted efficacy data are acceptable to support effectiveness of the product as a disinfectant against Pseudomonas aeruginosa ATCC 13388 on hard, non-porous surfaces at a 1:64 solution in the presence of 5% organic serum and 400 ppm AOAC hard water for a contact time of 3 minutes at 20 degrees Celsius.

Revise the FDA/EPA MOU disclaimer statement to reflect the latest version.

A stamped copy of the product labeling is enclosed for your records.

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

If you have any questions concerning this letter, please contact Ruth G. Douglas at (703)-305-7964.

Sincerely,



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

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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
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**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)



CALGON VESTAL LABORATORIES, INC.
SUBSIDIARY OF **MERCK**
& CO., INC.

ST. LOUIS, MISSOURI 63110

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 26 1995

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

1043-87

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 PHYSICIAN:** 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 wrung 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 autoclaved and disposed of according to local regulations for infectious disposal.

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 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.

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EPA Est. No. 1043-MO-1

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Vesphene II_x

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 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.

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 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.

Acinetobacter calcoaceticus, ATCC 19606

Candida albicans, Clinical Isolate

Candida parapsilosis, Clinical Isolate

Citrobacter freundii, ATCC 8090

Enterobacter aerogenes, ATCC 13048

Enterobacter cloacae, ATCC 23355

Escherichia coli, ATCC 25922

Klebsiella pneumoniae, ATCC 13883

Multiply (Methicillin)-Resistant

Staphylococcus aureus (MRSA),

Clinical Isolate

Proteus mirabilis, Clinical Isolate

Proteus vulgaris, ATCC 13315

Pseudomonas aeruginosa, ATCC 27853

Pseudomonas cepacia, ATCC 25416

Salmonella typhi, ATCC 6539

Salmonella typhimurium, ATCC 14028

Serratia marcescens, ATCC 8100

Shigella flexneri, ATCC 12022

Shigella sonnei, ATCC 25931

Staphylococcus aureus, ATCC 25923

Staphylococcus epidermidis, ATCC 12228

Streptococcus faecalis, ATCC 19433

Streptococcus pyogenes, ATCC 19615

Vesphene II_x is effective in 3 minutes at 20°C against *Pseudomonas aeruginosa* ATCC 13388, according to the A.O.A.C. Use Dilution Test when diluted with 400 ppm hard water to make a 1:64 (2 ounces per gallon) solution, in the presence of 5% added organic soil (serum).

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.

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 solution (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_x - For use with listed electrically conducted flooring of the vinyl type. 942P.

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