

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (TS-767)
WASHINGTON, DC 20460

EPA REGISTRATION NO.

DATE OF ISSUANCE

1043-115

NOV 2 1995

TERM OF ISSUANCE

NOTICE OF PESTICIDE: REGISTRATION
 REREGISTRATION

(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

NAME OF PESTICIDE PRODUCT

Process Vesphene® II_{st}

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

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

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

- a. Add the phrase "EPA Registration No. 1043-115."
- b. On the Center Panel, revise the heading "STATEMENT OF PRACTICAL STATEMENT" to read, "STATEMENT OF PRACTICAL TREATMENT." Under this heading, change "flush with after" to read, "flush with water."

3. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

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If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,



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

Enclosures

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CENTER PANEL

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 2 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.
1043-115

PROCESS VESPHENE® II_{st}

**ONE-STEP IN THE PRESENCE OF SERUM
GERMICIDAL DETERGENT
EPA REG. NO. 1043-XXX
FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY**

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

Active Ingredients

Sodium o-phenylphenate	10.16%
Sodium p-tertiary amylphenate	8.78%
Inert Ingredients	81.06%

KEEP OUT OF REACH OF CHILDREN

DANGER:

STATEMENT OF PRACTICAL STATEMENT

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 statements.

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

(LOGO)

**CALGON VESTAL LABORATORIES, INC.
ST. LOUIS, MISSOURI 63110**

495

ACCEPTED
with COMMENTS
In EPA Letter Dated:

NOV 2 1985

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.
1043-115

LEFT PANEL

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. (30 cc) 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 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

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 opening burning.

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EPA Est. No. 1043-MO-1

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RIGHT PANEL

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 germicidal detergent is intended for use on washable hard non-porous environmental surfaces such as floors, walls, counters, tools, carts and other equipment in cleanrooms, pharmaceutical plants and in other areas where anti-bacterial control measures are necessary.

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 20°C.

Acinetobacter calcoaceticus, ATCC 19606	Multiply (Methicillin)-Resistant	Serratia marcescens, ATCC 8100
Candida albicans, Clinical Isolate	Staphylococcus aureus (MRSA),	Shigella flexneri, ATCC 12022
Candida parapsilosis, Clinical Isolate	Clinical Isolate	Shigella sonnei, ATCC 25931
Citrobacter freundii, ATCC 8090	Proteus mirabilis, Clinical Isolate	Staphylococcus aureus, ATCC 25923
Enterobacter aerogenes, ATCC 13048	Proteus vulgaris, ATCC 13315	Staphylococcus epidermidis, ATCC 12228
Enterobacter cloacae, ATCC 23355	Pseudomonas aeruginosa, ATCC 27853	Streptococcus faecalis, ATCC 19433
Escherichia coli, ATCC 25922	Salmonella typhi, ATCC 6539	Streptococcus pyogenes, ATCC 19615
Klebsiella pneumoniae, ATCC 13883	Salmonella typhimurium, ATCC 14028	

FUNGICIDAL: Passes the 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 the A.O.A.C. Tuberculocidal Test [*Mycobacterium tuberculosis*, var. *bovis* (BCG)] 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 the Virucidal Assay (EPA Proposed Method) [Influenza A₂ (Japan), Herpes Simplex Type 2, Vaccinia Virus, 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), in 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. PROCESS VESPHENE II, - For use with listed electrically conducted flooring of the vinyl type. 942P.

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