

**NOTICE OF PESTICIDE:** REGISTRATION  
 REREGISTRATION*(Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended)***NAME OF PESTICIDE PRODUCT:**Vesta-Syde Interim Instrument  
Decontamination Solution**NAME AND ADDRESS OF REGISTRANT (Include ZIP code)**

┌	Calgon Vesta Laboratories Division of Calgon Corporation P.O. Box 117 Pittsburgh, Pa. 15201	└
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**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 notice is given in accordance with section 3(a)(1) of the Act, provided that:

1. The registrant shall file with the Agency for registration (reregistration) of your product under section 3(a)(1) or 3(a) such data as the Agency requires, all of which shall be available to the public upon request.

2. The registrant shall file with the Administrator, upon request, the following information:

a. The name of the registrant, "Calgon Vesta Laboratories, Inc., 117-117."

b. The name of the pesticide, "Vesta-Syde Interim Instrument Decontamination Solution, 117-117." and such data as such as Personal Data, Health Hazard, Contact Time, etc., to be made available to the public upon request by letter or otherwise.

3. The registrant shall file with the Administrator, upon request, the following information:

**BEST AVAILABLE COPY** ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

4. The previous efficacy data submitted for bactericide and tuberculocide will support the label claim for 1:128 dilution in the presence of 5 percent blood serum and 400 ppm of hard water for a contact time of 10 minutes.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 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.

*WCF*

Walter C. Francis  
Acting Product Manager (32)  
Antimicrobial Program Branch  
Registration Division (H7505C)

Enclosures

**BEST AVAILABLE COPY**

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DEC 17 1980

~~Trade Name of Instrument,  
Preparation and Instructions  
Furnished for the Practitioner  
Registered with the FDA, Reg. No.~~

KILLS HIV-1(AIDS  
VIRUS) ON INANIMATE  
SURFACES. +

FRONT PANEL

VESTA-SYDE<sup>®</sup> INTERIM INSTRUMENT DECONTAMINATION SOLUTION

1043-114

EFFECTIVE IN THE PRESENCE OF SERUM AND HARD WATER

EPA REG. NO. 1043-RRU  
EPA EST. NO. 1043-MO-1  
FOR INSTITUTIONAL USE ONLY

For Interim Instrument Decontamination Prior to Terminal  
Cleaning and Sterilization of Surgical Instruments and  
Apparatus.

Active Ingredients:

o-phenylphenol.....8.55%  
p-tertiary amyphenol.....7.36%

Inert Ingredients.....84.09

KEEP OUT OF REACH OF CHILDREN  
DANGER

STATEMENT OF PRACTICAL TREATMENT

If swallowed: Drink promptly a large quantity  
of water. Do not induce vomiting. Avoid alcohol. Get  
medical attention. If in Eyes: Flush with plenty of  
water for 15 minutes. Get medical attention. If on  
Skin: Wash with plenty of soap and water. Get  
medical attention if irritation persists. NOTE TO  
PHYSICIAN: probable mucosal damage may contraindicate  
the use of gastric lavage.

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

**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.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**DECONTAMINATING SOILED SURGICAL INSTRUMENTS AND APPARATUS:** This product is formulated for use in conjunction with Vesta-Syde Enzyme Presoak Solution. Vesta-Syde Enzyme Presoak should be diluted 2 ounces per gallon of water (1:64) and minimum 20-minute exposure time should be allowed for the Enzyme Presoak to work sufficiently to loosen proteinaceous soils. After a minimum 20-minute exposure to Vesta-Syde Enzyme Presoak, 2-ounces per gallon (1:64) of Vesta-Syde Interim Instrument Decontamination Solution should be deposited in the same vessel holding the soiled instruments and presoak solution. Gently stir the solution to provide a uniform mixture and thorough contact with the treated surfaces. Allow a minimum 20 minutes contact time to achieve interim instrument decontamination and disinfection on all soiled instruments and apparatus deposited in the vessel. Avoid splashing and cover, where possible, when transporting soiled instruments.

This material is formulated for use in an interim step prior to subsequent cleaning and sterilization or disinfection of instruments and apparatus. Use only with Vesta-Syde Enzyme Presoak. Do not add other chemicals. Not recommended for prolonged storage of instruments.

**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:**

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LEFT PANEL (cont'd)

**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 solution (1 fl.oz. per 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**

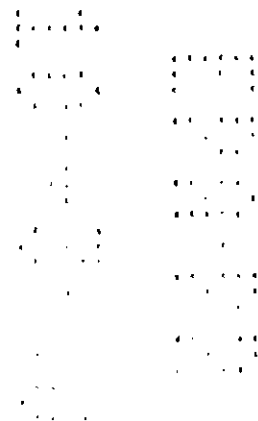
**PROHIBITIONS:** Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

**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 pesticide containers.

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



Division of Calgon Corporation  
Subsidiary of MERCK & Co., Inc.  
St. Louis, Missouri 63133



## RIGHT PANEL

Vesta-Syde Interim Instrument Decontamination Solution represents a research-developed, state-of-the-art compound for use with Vesta-Syde Enzyme Presoak as part of an interim instrument decontaminating step for soiled surgical instruments and apparatus. It substantially reduces the risk of exposure once surgery is completed. This product is effective in both hard water and in the presence of 5% blood serum. It is formulated as a concentrate for use in conjunction with the enzyme presoak. Its unique formulation allows for the addition of this product into the soiled instrument container in surgical suites, or other procedure areas.

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

**INTERIM INSTRUMENT DECONTAMINATION/DISINFECTION PRIOR TO TERMINAL CLEANING AND STERILIZATION TO SIGNIFICANTLY REDUCE THE RISK OF CROSS CONTAMINATION:** When tested according to a protocol which comprised simulated contamination of instruments with a slurry containing proteinaceous matter derived from beef tissue and sheep's blood (50% by volume) containing A.O.A.C. specified concentrations of S. aureus, S. choleraesuis, Ps. aeruginosa dried then exposed to Vesta-Syde Enzyme Presoak diluted 1:64 in 400 ppm A.O.A.C. hard water for 20 minutes followed by the addition of Vesta-Syde Interim Instrument Decontamination Solution at a 1:64 dilution in the enzyme presoak solution completely inactivated S. aureus, S. choleraesuis, and Ps. aeruginosa in replicate tests in 20 minutes at 25°C (room temperature).

**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.

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RIGHT PANEL (cont'd p. 2)

Acinetobacter calcoaceticus, ATCC 19606  
Candida albicans, Clinical isolate  
Candida parapsilosis, Clinical isolate  
Citrobacter freundii, ATCC 3090  
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  
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

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

RIGHT PANEL (cont'd p.3)

**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 A (Japan), Herpes simplex Type 2, Vaccinia and Adenovirus Type 2) 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.



FRONT PANEL

CALGON VESTAL LABORATORIES

VESTA-SYDE<sup>®</sup> ENZYME PRESOAK SOLUTION

FOR SURGICAL INSTRUMENTS AND APPARATUS

SEE BACK PANEL FOR USE INSTRUCTIONS AND PRECAUTIONS

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



Division of Calgon Corporation  
Subsidiary of Merck & Co., Inc.  
St. Louis, Missouri 63133

BACK PANEL

VESTA-SYDE<sup>®</sup> ENZYME PRESOAK SOLUTION

FOR USE WITH VESTA-SYDE INTERIM INSTRUMENT DECONTAMINATION SOLUTION

Vesta-Syde Enzyme Presoak is formulated for use on all surgical instruments and apparatus where blood, protein, and mucous form hard to remove soils or where scrubbing is impractical. This material is formulated for use as the first two steps for interim instrument decontamination once surgery is completed. Vesta-Syde Enzyme Presoak has no biocidal efficacy, and is formulated for use as a digesting agent in proteinaceous soils. Equipment should be sterilized or disinfected by appropriate methods in separate subsequent steps.

**DIRECTIONS:** Dilute 2 ounces of Vesta-Syde Enzyme Presoak per gallon of water in the dirty instrument catch basin or instrument tray. Allow a minimum of 20 minutes contact time as a presoak for optimum results. After soaking for 20 minutes, add 2 ounces of Vesta-Syde Interim Instrument Decontamination Solution and allow an additional 20 minutes for the decontamination step to take place. If ultrasonic cleaning is desired, Vesta-Syde Enzyme Presoak may be used in an ultrasonic cleaning system. Allow a minimum of 20 minutes agitation time when using. Use only in conjunction with Vesta-Syde Interim Instrument Decontamination Solution. Do not add other chemicals. Added chemicals may destroy the effectiveness of this product.

**WARNING:** Contains subtilisins (proteolytic enzymes), CAS #9014-01-01. Mild eye and skin irritant. Avoid generating and breathing mists. Wear eye protection and gloves when handling. Do not get in eyes, on skin, or clothing. Do not allow product to dry on clothing: rinse and launder immediately. Clean up spills immediately. In rare instances, allergic respiratory sensitization has resulted from chronic or subchronic exposures to dusts or mists. Wash hands thoroughly after use. Keep containers closed when not in use. Keep out of reach of children.

**FIRST AID:**

**Eyes:** In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. See a physician.

**Skin:** Immediately wash with soap and plenty of water for at least 15 minutes and remove any contaminated clothing. If irritation develops, seek medical attention.

**Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Seek medical aid. Report all inhalation exposures to Health and Safety Personnel. **Ingestion:** If swallowed, do not induce vomiting. Give water to dilute. Call a physician. Never give anything by mouth to an unconscious person.

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