

FEB 1 1992

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

Dear Mr. Ebers:

Subject: Vesta-Syde Interim Instrument Decontamination Solution
EPA Registraton No. 1043-114
Your Resubmission Dated September 14, 1992

This is in response to your resubmission of above date submitting corrected labeling for the foil packets, packaging and enzyme pre-soaks and storage stability data.

The following comments apply:

1. The submitted accelerated storage and stability data of 30 days 50 °C is acceptable on an interim basis. The results of 12 months storage and stability data should be submitted within 15 months after the granting of this approval.
2. On the Vesta-Syde Enzyme Pre-Soak label, the ingredient statement is not required to be given. However, if you wish to list ingredients then list them all and delete from the label the headings Active Ingredient and Inert Ingredients.
3. The submitted chemical composition of Vesta-Syde Pre-Soak is acceptable.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records. Five copies of the finished labeling must be submitted before you release the product for shipment bearing the amended labeling.

CONCURRENCES							
SYMBOL	NH-150FC						
SURNAME	W. Puryle						
DATE	12-10						

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Please note that the Vesta-Syde Enzyme Pre-Soak label is not being stamped accepted because it is not considered a pesticide. We do not stamp non-pesticidal labeling. Accordingly, there should not be an EPA Registration No. on the label.

If you have any further questions, please contact Ms. Barbara Pringle at (703)305-6484.

Sincerely,



Ruth G. Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

**FRONT PANEL
FOIL PACKET**

**VESTA-SYDE®
INTERIM INSTRUMENT**

DECONTAMINATION SOLUTION

EFFECTIVE IN THE PRESENCE OF SERUM AND HARD WATER

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

**EPA REG. NO. 1043-114
EPA EST. NO. 1043-MO-1**

FOR INSTITUTIONAL USE ONLY

Active Ingredients:

- o-phenylphenol..... 8.55%**
- p-tertiary amylphenol..... 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.

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.

NET CONTENTS: 2.0 FL.OZ. (59.2 mL)

**ACCEPTED
with COMMENTS
by EPA Letter Docket**

FEB 10 1993

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

1043-114

**BACK PANEL
FOIL PACKET**

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. Vesta-Syde Enzyme Presoak should be diluted 2 ounces per gallon of water (1:64) and a minimum 20 minute exposure time should be allowed for the Enzyme Presoak to work sufficiently to loosen proteinaceous soils. After 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.

KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in healthcare 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, mask 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

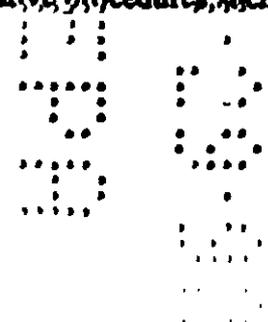
Prohibitions: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

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 land fill approved for pesticides.

Container Disposal: Do not reuse empty pouch. Wrap pouch and put in trash.

General: Consult federal, state or local disposal authorities for approved alternative procedures, such as limited open burning.

Refer to package insert for additional product information.



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**VESTA-SYDE INTERIM INSTRUMENT
DECONTAMINATION SOLUTION
PACKAGE INSERT**

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 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% 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 dilution 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.

- 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

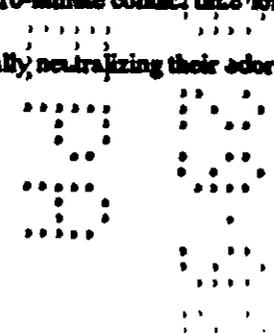
FUNGICIDAL: Passes A.O.A.C. Fungicidal Test (*T. mentagrophytes*) when diluted with 400 ppm hard water to make a 1:128 (1 ounce per 1 gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 20°C.

TUBERCULOCIDAL: Passes A.O.A.C. Tuberculocidal Test (*Mycobacterium tuberculosis* var. *bovis*) when diluted with 400 ppm 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) 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°. Although efficacy at a 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.



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