

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. Use only with Vesta-Syde Enzyme Presoak. Do not add other chemicals. Not recommended for prolonged storage of instruments.

EPA Reg. No. 1043-114

EPA Est. No. 11563-MI-1

FOR INSTITUTIONAL USE ONLY

Active Ingredients:

o-phenylphenol.....9.09%

p-tertiary amylphenol.....7.66%

Inert Ingredients.....83.25%

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.

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. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

NET CONTENTS: 2.0 fl. oz. (59.2 ml)

DIRECTION 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 a minimum 20 minute exposure to Vesta-Syde Enzyme Presoak, 2 ounces per gallon (1:64) of Vesta-Syde Instrument Decontamination Solution should be deposited in the same vessel holding the soiled instruments and enzyme 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 on all soiled instruments and apparatus deposited in the vessel. Avoid splashing and cover, where possible, when transporting soiled 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:
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 20-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

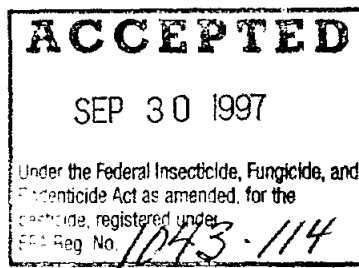
PROHIBITIONS: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

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: 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.

(Logo) STERIS Corporation
CALGON VESTAL Division
St. Louis, MO 63110 U.S.A.



PRODUCT MADE IN U.S.A.

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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 suits or other procedure areas.

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. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

Although efficacy was shown at various dilutions and contact times, use this product at a 1:64 dilution for a 20 minute contact time for use against all of the organisms claimed.

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

INTERIM INSTRUMENT DECONTAMINATION/DISINFECTION PRIOR TO TERMINAL CLEANING AND STERILIZATION TO 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*, and *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 8090

Enterobacter aerogenes, ATCC 13048

Enterobacter cloacae, ATCC 23355

Escherichia coli, ATCC 25922

Klebsiella pneumoniae, ATCC 13883

Staphylococcus aureus, (MRSA),

Multiply (Methicillin)-Resistant

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

Vesta-Syde Interim Instrument Decontamination Solution 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.

VIRUCIDAL: Passes 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 20-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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CALGON VESTAL Division
St. Louis, MO 63110 U.S.A.

ACCEPTED

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the products registered under No. 1093-114