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.

FOR INSTITUTIONAL USE ONLY

Active Ingredients	Α	ctive	Ing	redi	ents
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o-phenylphenol	9.09%
p-tertiary amylphenol	
Inert Ingredients	
Total	100.00%

KEEP OUT OF REACH OF CHILDREN DANGER

	DIE GER
	FIRST AID
If inhaled	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
If on skin or clothing	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If in eyes	*Hold eye open and rinse slowly and gently with water for 15-20 minutes. *Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. *Call a poison control center or doctor for treatment advice.
If swallowed	Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
	HOTLINE NUMBER stuct container or label with you when calling a poison control center or
	ng for treatment.
	NOTE TO PHYSICIAN
Probable muc	osal damage may contraindicate the use of gastric lavage.

PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS: DANGER

Corrosive. Causes eye damage or skin burns. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin, or on clothing. Avoid brathing spray mist. Wear goggles or face shield (safety glasses), protective clothing and chemical resistant gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before use.

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:

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

Store in a cool dry place. Do not reuse empty pouch. Wrap pouch and put in trash.

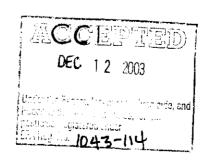
STERIS Corporation

7501 Page Avenue St. Louis, MO 63133 U.S.A.

EPA Reg. No. 1043-114

EPA Est. No. 11563-MI-1

PRODUCT MADE IN U.S.A.



ENZYME PRESOAK

FOR SURGICAL INSTRUMENTS AND APPARATUS

Active Ingredients:

 Bacterial Protease
 0.20%

 Inert Ingredients
 99.80%

 Total
 100.00%

CA Reg. No. 1043-50001

SEE BACK PANEL FOR USE INSTRUCTIONS AND ADDITIONAL PRECAUTIONS

KEEP OUT OF REACH OF CHILDREN

DANGER

	FIRST AID
If inhaled	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
If on skin or clothing	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. Call a poison control center or doctor for treatment advice.
wallowed	-Call poison control center or doctor immediately for treatment advice. -Have person sip a glass of water if able to swallow. -Do not induce vomiting unless told to do so by the poison control center or doctor. -Do not give anything by mouth to an unconscious person.
	HOTLINE NUMBER Iduct container or label with you when calling a poison control
	ctor, or going for treatment. NOTE TO PHYSICIAN cosal damage may contraindicate the use of gastric lavage.

Patent Number 5,489,531

STERIS Corporation

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NET CONTENTS:

ENZYME PRESOAK

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 of 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.

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 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. As with all ultrasonic cleansing procedures, the ultrasonic system should be covered. 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.

PRECAUTIONARY STATEMENT

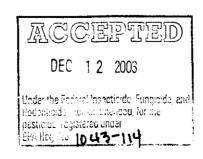
DANGER: Corrosive. Causes eye and skin damage. Wear goggles or face shield and rubber gloves when handling. Do not get in eyes, on skin, or clothing. Remove contaminated clothing; rinse and launder immediately. Clean up spills immediately. Wash hands thoroughly after use. Keep containers closed when not in use. Keep out of reach of children.

STORAGE AND DISPOSAL: Store in a cool dry place. Do not reuse empty pouch. Wrap pouch and put in trash.

Best if used before date on the pouch.

FOR INSTITUTIONAL USE ONLY.

NOT FOR HOME USE.



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.

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 activated 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

Proteus mirabilis, Clinical Isolate

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) plution, 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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