



GENERAL DESCRIPTION

Process Vesphene IIst Sterile Phenolic Disinfectant is a sterile, gamma irradiated phenolic detergent designed for pharmaceutical, biotechnology, medical device and other Food and Drug Administration (FDA) regulated facilities. It contains selected synthetic phenols blended with biodegradable synthetic detergents and builders.

Process Vesphene IIst Sterile Phenolic Disinfectant is an effective one-step cleaner when diluted one ounce per one gallon (0.8% v/v) with soft water or hard water up to 400 ppm hardness (as CaCO₃) in the presence of 5% blood serum.

Process Vesphene IIst disinfectant was specifically developed for use on hard, non-porous critical environment surfaces found in cleanrooms and other critical production areas including: hoods, equipment airlocks, gowning areas, barriers and isolators, and process equipment.

Process Vesphene IIst detergent can be used for one-step cleaning, disinfecting and deodorizing of stainless-steel surfaces and on a variety of plastics and elastomers commonly used in cleanrooms. It is also safe for use on concrete, resilient vinyl, asphalt, linoleum, rubber, terrazzo and other combination type floors.

FEATURES

Filtered to five micron
Double-bagged package
Gamma irradiated to a minimum of 2.5 Mrd (25 kGy)
Available in a one-gallon bottle or a convenient unit dose package

BENEFITS

Removes visible particulates
Facilitates handling in controlled areas
Validated to verify sterility (Validation Report available upon request)
Saves labor and time when used in a validated disinfection process

PHYSICAL PROPERTIES

Form..... Red liquid
Odor..... Mild and pleasant
Specific gravity (25°C [77°F]) 1.10 typical
pH (undiluted)..... 12.3 typical
pH (0.8% v/v)..... 10.6 typical

BACTERICIDAL PROPERTIES

The official test for determining the germicidal efficacy of a one-step cleaner disinfectant is the Use-Dilution Method as stated in the *Association of Official Analytical Chemists (AOAC) Methods of Analysis*. Process Vesphene IIst concentrate diluted one ounce per gallon (0.8% v/v) in 400 ppm (as CaCO₃) hard water is effective against the following microorganisms in the presence of 5% blood serum, 10 minutes at 20°C (68°F).

<i>Acinetobacter calcoaceticus</i>	ATCC 19606
<i>Candida albicans, Clinical Isolate</i>	
<i>Candida parapsilosis, Clinical Isolate</i>	
<i>Citrobacter freundii</i>	ATCC 8090
<i>Enterobacter aerogenes</i>	ATCC 13048
<i>Enterobacter cloacae</i>	ATCC 23355
<i>Escherichia coli</i>	ATCC 25922
<i>Klebsiella pneumoniae</i>	ATCC 13883
<i>Proteus mirabilis, Clinical Isolate</i>	
<i>Proteus vulgaris</i>	ATCC 13315
<i>Pseudomonas aeruginosa</i>	ATCC 15442

<i>Pseudomonas aeruginosa</i>	ATCC 27853
<i>Pseudomonas cepacia</i>	ATCC 25416
<i>Salmonella choleraesuis</i>	ATCC 10708
<i>Salmonella typhi</i>	ATCC 6539
<i>Salmonella typhimurium</i>	ATCC 14028
<i>Serratia marcescens</i>	ATCC 8100
<i>Shigella flexneri</i>	ATCC 12022
<i>Shigella sonnei</i>	ATCC 25931
<i>Staphylococcus aureus</i>	ATCC 6538
<i>Staphylococcus aureus</i>	ATCC 25923
<i>Staphylococcus aureus (MRSA), Multiply(Methicillin)-Resistant Clinical Isolate</i>	
<i>Staphylococcus epidermidis</i>	ATCC 12228
<i>Streptococcus faecalis</i>	ATCC 19433
<i>Streptococcus pyogenes</i>	ATCC 19615

FUNGICIDAL PROPERTIES

An official test for determining the fungicidal efficacy of a one-step cleaner disinfectant is the Fungicidal Test method as described in the *AOAC Methods of Analysis*, and modified as required by Environmental Protection Agency (EPA) regulations. Process Vesphene IIst concentrate diluted one ounce per gallon (0.8% v/v) in 400 ppm (as CaCO₃) hard water is effective against *Trichophyton mentagrophytes* in the presence of 5% blood serum, 10 minutes at 20°C (68°F).

TUBERCULOCIDAL PROPERTIES

Process Vesphene IIst germicidal detergent passes the *AOAC Tuberculocidal Test [Mycobacterium tuberculosis var. bovis (BCG)]* when diluted one ounce per gallon (0.8% v/v) with 400 ppm (as CaCO₃) hard water in the presence of 5% organic soil (serum) for 10 minutes at 20°C (68°F).

VIRUCIDAL PROPERTIES

Influenza A₂ (Japan), Herpes Simplex Type 2, Vaccinia, and Adenovirus Type 2 in the presence of 5% blood serum were inactivated by Process Vesphene IIst disinfectant diluted one ounce per gallon (0.8% v/v) in 400 ppm (as CaCO₃) hard water using the EPA accepted glass slide procedure for 10 minutes at 20°C (68°F).

When tested by an EPA approved dilution method, a dried film of HIV-1 (AIDS) virus, with added 10% organic soil (serum) was completely inactivated by a one ounce per gallon (0.8% v/v) solution of Process Vesphene IIst disinfectant in 400 ppm (as CaCO₃) hard water in one minute at 20°C (68°F). Although efficacy at one-minute contact time has been shown to be adequate for HIV-1, this time would not be sufficient for other organisms. Use a 10-minute contact time for all organisms.

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, Non-Porous Surfaces

Always remove gross filth and heavy soil before application of the use-dilution of this product. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution daily or when it becomes dirty, and replace with fresh solution. This is a complete product. Do not add other chemicals. Add one fluid ounce (30cc) to each premeasured gallon of water. Always add this product (concentrate) to premeasured water. For accurate solution preparation, use the STERIS's 1-Stroke Dispenser (one stroke delivers one ounce of product) or use the convenient unit dose package. If using the unit dose package, dispense the contents of the packet into premeasured water. Gently mix until the solution is uniform. Apply use-dilution to the surface being disinfected with a cloth, sponge, coarse spray, mop, or brush using normal cleaning methods. Allow the treated surfaces to remain wet for 10 minutes, then remove excess solution with a wrung-out applicator. Discard soiled solutions in an approved manner and replace with fresh use-dilutions. A properly prepared solution of Process Vesphene IIst disinfectant intended for use as a hard surface disinfectant has a shelf life of 14 days (use life) when stored in a closed container such as a spray bottle. This a complete product. Do not add other chemicals. Use only as directed on label.

STORAGE AND DISPOSAL

Storage

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty containers. This product should be stored in an area where it is not exposed to extreme temperatures.

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. Triple rinse and deposit in a waste container for incineration, or in a landfill approved for pesticide containers. Consult federal, state, or local disposal authorities for approved alternative procedures, such as limited open burning.

SERVICE

Sales

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing telephone support, telephone and video conferencing, and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

PRECAUTIONS

Information concerning human and environmental exposure for the product may be reviewed on the Material Safety Data Sheet and the label. For additional information regarding incidents involving human and environmental exposure, call 1-314-535-1395.

For further information, please contact:

STERIS[®] STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-548-4873
www.steris.com

