

GENERAL DESCRIPTION

One Solution st™ Vesphene™ III Premeasured WFI is a unique product offering which provides convenience, time savings, and cost reduction. One Solution st Vesphene III Premeasured WFI formula is composed of a one gallon bottle of sterile Water for Injection (WFI) and a convenient unit dose package of sterile Vesphene IIIst Phenolic Disinfectant which when blended provides a powerful disinfectant solution which is ready to use with no additional processing required. One Solution st Vesphene III Premeasured WFI formula 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 synthetic detergents and builders.

One Solution st Vesphene III Premeasured WFI is an effective one-step cleaner when diluted one oz/gal (0.8% v/v) with soft or hard water up to 400 ppm hardness (CaCO₃) in the presence of 5% blood serum.

One Solution st Vesphene III Premeasured WFI 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, process equipment and piping systems.

One Solution st Vesphene III Premeasured WFI 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.

The WFI used in the One Solution st Vesphene III Premeasured WFI meets all United States Pharmacopeia (USP) WFI requirements.

FEATURES

BENEFITS

Vesphene IIIst Phenolic Disinfectant	Broad-spectrum germicidal effectiveness at one oz/gal (0.8%), no revalidation required for current Vesphene IIIst and Vesphene IIIse users
Double-bagged package	Facilitates handling in controlled areas
Gamma irradiated to a minimum of 2.5 Mrd (25 kGy)	Validated to verify sterility (Validation Report Summary available upon request)
One gallon WFI and unit dose packet of Vesphene IIIst Phenolic Disinfectant	Saves labor and time; no filtration required

PHYSICAL PROPERTIES

Form	Red liquid
Odor.....	Mild and characteristic
Specific Gravity (25°C [77°F]).....	1.11, typical
pH (Undiluted)	12.5, typical
pH (1:128 Dilution).....	10.6, typical
Flash Point	>200°F (93.33°C) Tag Closed Cup (TCC)

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 AOAC Methods of Analysis. One Solution st Vesphene III Phenolic Disinfectant 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.

<i>Acinetobacter baumannii</i>	ATCC 19606
<i>Burkholderia cepacia</i>	ATCC 25416
<i>Enterobacter cloacae</i>	ATCC 13047

<i>Escherichia coli</i>	ATCC 25922
<i>Listeria monocytogenes</i>	ATCC 19111
<i>Micrococcus yunnanensis</i>	ATCC 7468
<i>Mycoplasma gallisepticum</i>	ATCC 15302
<i>Pseudomonas aeruginosa</i>	ATCC 15442
<i>Serratia marcescens</i>	ATCC 14756
<i>Staphylococcus aureus</i>	ATCC 6538
<i>Staphylococcus epidermidis</i>	ATCC 12228
<i>Streptococcus pyogenes</i>	ATCC 19615

FUNGICIDAL PROPERTIES

The official test for determining the fungicidal efficacy of a one-step cleaner disinfectant is the AOAC Fungicidal Method as described in the AOAC Methods of Analysis and modified as required by Environmental Protection Agency (EPA) regulations. One Solution st Vesphene III Phenolic Disinfectant diluted one ounce per gallon (0.8% v/v) in 400 ppm (as CaCO₃) hard water is effective against *Trichopyton interdigitale* (ATCC 9533) in the presence of 5% blood serum, 10 minutes at 20°C.

TUBERCULOCIDAL PROPERTIES

One Solution st Vesphene III Phenolic Disinfectant passes the AOAC Tuberculocidal Test Method 965.12 (*Mycobacterium tuberculosis var. bovis* [BCG]) when diluted one ounce per gallon (0.8% v/v) with 400 ppm AOAC hard water in the presence of 5% organic soil (serum), 10 minutes at 20°C.

VIRUCIDAL PROPERTIES

When using the EPA Proposed Method (ASTM 1053-11), One Solution st Vesphene III Phenolic Disinfectant is effective against the following viruses when diluted with 400 ppm AOAC hard water to make a 1:128 (one ounce per one gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 20°C.

- Human Immunodeficiency Virus Type 1 (HIV-1)
- Influenza A2 Virus (H2N2) A/2/Japan/305/57 (Charles River Laboratories)
- Adenovirus Type-2 Strain (ATCC VR-846)
- Avian Influenza A Virus Strain (H9N2)
- Feline Calicivirus, Strain: F9 (ATCC VR-782) (Surrogate for Human Norovirus)

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 premeasured one fl oz (30 cc) from unit dose pouch to each premeasured gallon of WFI. Gently mix. 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. This is a complete product. Do not add other chemicals. Use only as directed on label.

Kills HIV on precleaned environmental surfaces/objects previously soiled with blood and bodily fluids in settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or bodily fluids, and which the surfaces/objects likely to be soiled with blood or bodily fluids can be associated with potential for transmission of human immunodeficiency virus Type HIV-1 (associated with AIDS).

Special Instructions for Cleaning and Decontamination Against HIV-1 (Human Immunodeficiency Virus or AIDS virus) on Surfaces/Objects Soiled with Blood/Bodily Fluids

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks, and eye coverings.

Cleaning Procedure: Blood and other bodily fluids must be thoroughly cleaned from surfaces and objects before application of a 1:128 use-solution (one ounce per one gallon). Prepare and apply solution as directed in paragraph above.

Contact Time: Allow treated surfaces to remain wet for 10 minutes.

Infectious Materials Disposal: Blood and other bodily fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Do not store near heat or open flame. If frozen, thaw and re-mix before use.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal

(For Packet:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or dispose in sanitary landfill or by other procedures approved by state and local authorities.

(For <5 gal:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or dispose in sanitary landfill or by other procedures approved by state and local authorities. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full of water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank to store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

(For >5 gal:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or dispose in sanitary landfill or by other procedures approved by state and local authorities. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full of water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

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 both telephone 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 may be reviewed on the Safety Data Sheet (SDS) for the product. For additional information regarding incidents involving human and environmental exposure, call 1-800-424-9300.

For further information, please contact:



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