

GENERAL DESCRIPTION

One Solution st™ LpH™ III Premeasured WFI Phenolic Disinfectant is a unique product offering which provides convenience, time savings, and cost reduction. One Solution st LpH III Premeasured WFI is composed of a one-gallon bottle of sterile Water for Injection (WFI) and a convenient unit dose package of sterile LpH III st Phenolic Disinfectant which when blended provides a powerful disinfectant solution which is ready to use with no additional processing required. One Solution st LpH III Premeasured WFI 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 LpH 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 LpH III Premeasured WFI was specifically developed for use on hard, non-porous environment surfaces found in cleanrooms and other production areas.

One Solution st LpH III Premeasured WFI can be used for one-step cleaning, disinfecting and deodorizing of stainless or galvanized steel and chrome surfaces and on a variety of plastics commonly used in cleanrooms. It is also safe for use on sealed concrete, resilient vinyl, linoleum, rubber, glazed terrazzo, and other non-porous environmental surfaces.

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

FEATURES

BENEFITS

LpH III st Phenolic Disinfectant

Broad spectrum germicidal effectiveness at one oz/gal (0.8%); no revalidation required for current LpH III st and LpH III se users

Double-bagged package

Facilitates handling in controlled areas

Gamma irradiated to a minimum of 2.5 Mrd (25kGy)

Validated to verify sterility (Validation Report Summary available upon request)

One-gallon WFI and unit dose packet of LpH III st Phenolic Disinfectant

Saves labor and time; no filtration required

PHYSICAL PROPERTIES

Form	Clear, light straw to dark amber
Odor	Mild and characteristic
Specific Gravity (25°C [77°F])	1.114 typical
Typical pH (undiluted).....	0.25 typical
Typical pH (1:128 dilution).....	2.1 Typical
Flash Point	>90°F (32.22°C) Closed Cup

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. LpH III st Phenolic Disinfectant 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.

<i>Acinetobacter baumannii</i>	ATCC 19606
<i>Enterobacter cloacae</i>	ATCC 13047
<i>Escherichia coli</i>	ATCC 25922
<i>Micrococcus yunnanensis</i>	ATCC 7468
<i>Serratia marcescens</i>	ATCC 14756
<i>Staphylococcus aureus</i>	ATCC 6538
<i>Pseudomonas aeruginosa</i>	ATCC 15442

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 EPA regulations. LpH III st Phenolic Disinfectant diluted one ounce per gallon (0.8% v/v) in 400 ppm as (CaCO₃) hard water is effective against *Trichophyton interdigitale* (ATCC 9533) in the presence of 5% blood serum, 10 minutes at 20°C.

TUBERCULOCIDAL PROPERTIES

LpH III st 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) in 400 ppm as (CaCO₃) hard water in the presence of 5% blood serum, 10 minutes at 20°C.

VIRUCIDAL PROPERTIES

When using the EPA Proposed Method (ASTM 1053-11), LpH III st Phenolic Disinfectant is effective against the following viruses when diluted one ounce per gallon (0.8% v/v) in 400 ppm as (CaCO₃) hard water in the presence of 5% blood serum, 10 minutes at 20°C.

Human Immunodeficiency Virus (HIV-1)
Influenza A2 Virus (H2N2) A/2/Japan/305/57 (Charles River Laboratories)
Adenovirus Type 2 (ATCC VR 846)
Avian Influenza Virus (H9N2)

This product was tested using the Virucidal Assay (EPA Proposed Method) against *Feline calicivirus* (surrogate for *Human Norovirus*) strain: F9, ATCC VR-782 and it passed when diluted with 400 ppm AOAC hard water to make a 1:64 (one ounce per 64 ounces) solution in the presence of 5% organic soil (serum), 10 minutes at 20 °C.

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:

To make a solution, add one fluid ounce (30 cc) of product per each premeasured gallon of water used (0.8% v/v) and gently mix. Always add this product (detergent) to premeasured water. Apply solution with a cloth, sponge, mop, brush or coarse spray using normal cleaning methods. Allow treated surfaces to soak for 10 minutes, then remove excess solution with a wrung-out applicator. Prepare a fresh dilution at least daily or as solution becomes dirty, discard and replace with a fresh one. Before cleaning begins, always sweep or dust mop area to be cleaned thoroughly, removing any gross filth. This is a complete product. Do not add or dilute with other chemicals. If frozen, thaw and re-mix before use. Use only as directed.

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: HIV-1 virus is inactivated in 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 food, feed or water by storage or disposal.

Pesticide Storage: Do not store near heat or open flame. If frozen, thaw and remix 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 with 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 with 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 314-535-1395.

For further information, please contact:



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