



GENERAL DESCRIPTION

Process LpH st Sterile One-Step Cleaner Disinfectant is a sterile, gamma irradiated phenolic germicidal detergent designed for pharmaceutical, biotechnology, medical device and other FDA regulated facilities. This advanced non-alkaline formula is a proven high level disinfectant in both hard water and 5% organic serum. The use-solution of this product, when diluted 1/2 oz/gal of water (0.4%), is formulated to clean, disinfect and deodorize in a simple one-step process.

Process LpH st 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 cleaners.

Process LpH st disinfectant 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

Proven LpH st disinfectant formula
Filtered to five micron
Double-bagged package
Gamma radiated to a minimum of 2.5 Mrd (25 kGy)

Available in a one-gallon bottle or a convenient unit dose package

BENEFITS

Broad spectrum germicidal effectiveness at 1/2 oz/gal (0.4%)
Removes visible particulates
To facilitate handling
Validated to verify sterility (Validation Report available upon request)

Saves labor and time when used in a validated disinfection process

PHYSICAL PROPERTIES

Form..... Amber to yellow
Odor..... Mild and pleasant
Specific gravity (25°C [77°F])..... 1.11 typical
pH (undiluted)..... Approximately 1.0
pH (0.4% v/v)..... 2.6 typical
Flash point (tag closed cup)..... 44°C (111°F)
Gamma irradiation dosage..... 2.5 Mrd (25kGy) min.
Filtration Five micron filter

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*. Process LpH st disinfectant concentrate diluted 1/2 oz/gal (0.4%) in 400 ppm (CaCO₃) hard water is effective against the following microorganisms in the presence of 5% blood serum, in 10 minutes at 20°C (68°F).

| | |
|------------------------------------|------------------|
| <i>Acinetobacter calcoaceticus</i> | ATCC 19606 |
| <i>Aeromonas hydrophila</i> | ATCC 7965 |
| <i>Bordetella avium</i> | ATCC 35086 |
| <i>Campylobacter jejuni</i> | ATCC 29428 |
| <i>Candida albicans</i> | Clinical Isolate |
| <i>Candida parapsilosis</i> | Clinical Isolate |
| <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>Listeria monocytogenes</i> | ATCC 15313 |
| <i>Mycoplasma gallisepticum</i> | ATCC 19610 |
| <i>Pasteurella multocida</i> | ATCC 29977 |
| <i>Proteus mirabilis</i> | Clinical Isolate |
| <i>Proteus vulgaris</i> | ATCC 13315 |
| <i>Pseudomonas aeruginosa</i> | ATCC 15442 |
| <i>Pseudomonas aeruginosa</i> | ATCC 27853 |
| <i>Salmonella choleraesuis</i> | ATCC 10708 |
| <i>Salmonella enteritidis</i> | ATCC 13076 |
| <i>Salmonella sp. Serovar pullorum</i> | ATCC 19945 |
| <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</i> (MRSA), Multiply (Methicillin)-Resistant | Clinical Isolate |
| <i>Staphylococcus epidermidis</i> | ATCC 12228 |
| <i>Streptococcus faecalis</i> | ATCC 19433 |
| <i>Streptococcus pyogenes</i> | ATCC 19615 |
| <i>Streptococcus suis</i> | ATCC 43765 |

FUNGICIDAL PROPERTIES

The official test for determining the fungicidal efficacy of a one-step cleaner disinfectant is the Use Dilution Method as described in the *AOAC Methods of Analysis*, and modified as required by EPA regulations. Process LpH st disinfectant concentrate diluted 1/2 oz/gal (0.4%) in 400 ppm (as CaCO₃) hard water is effective against *Trichophyton mentagrophytes* in the presence of 5% blood serum, in 10 minutes at 20°C (68°F).

TUBERCULOCIDAL PROPERTIES

Process LpH st disinfectant passes the AOAC Tuberculocidal Test (*Mycobacterium tuberculosis var. bovis [BCG]*) when diluted 1/2 oz/gal (0.4%) with 400 ppm AOAC hard water in the presence of 5% organic soil (serum), 10 minutes at 20°C (68°F).

VIRUCIDAL PROPERTIES

When using the EPA Proposed Method, Process LpH st is effective against the following viruses at a 1/2 oz/gal (0.4%) dilution in 400 ppm hard water, and 5% serum in 10 minutes at 20-25°C (68-77°F).

| | |
|------------------------------|----------------------------------|
| Adenovirus Type 2 | Influenza A ₂ (Japan) |
| Herpes Simplex Type 2 | Newcastle Disease |
| Infectious Bronchitis | Transmissible Gastroenteritis |
| Infectious Laryngotracheitis | Vaccinia Virus |

When tested by an EPA approved Dilution Method, a dried film of HIV-1 (AIDS) virus with added 5% organic soil (serum) was completely inactivated by a 1/2 oz/gal (0.4%) solution of Process LpH st disinfectant in 400 ppm AOAC hard water in 60 seconds 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-solution of this product. Add 1/2 fluid ounce 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 1/2 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-solution 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-solutions. This a complete product. Do not add other chemicals. Use only as directed on label.

Fogging as an Adjunct to Regular Cleaning and Disinfecting

This product may be used in fogging (wet misting) as an adjunct either preceding or following regular cleaning and disinfecting procedures in research and manufacturing facilities. Thoroughly clean all surfaces. Fog the desired area at 32 to 64 ounces of use dilution per 1000 cubic feet using equipment with an automatic timer. Do not remain in treated areas; allow at least two hours after fogging is complete before re-entering fogged area. Before fogging, remove or cover any packaging material with waterproof coverings. Treated surfaces must be thoroughly scrubbed with Process LpH st disinfectant at a 1/2 oz/gal (0.4%) dilution and rinsed with water before reuse. Do not employ equipment until treatment has dried.

SPECIAL INSTRUCTION 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 1/2 oz/gal (0.4%) use-solution. Prepare and apply solution as directed in paragraph above.

Contact Time

While the HIV-1 virus is inactivated in one minute, use a 10-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

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 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 Material Safety Data Sheet (MSDS) 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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