

8714-8

08/30/2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

August 30, 2007

David H. Dawe  
SciReg, Inc.  
12733 Director's Loop  
Woodbridge, VA 22192

Subject: Pharmacal Research Laboratories, Inc.  
Clidox-S Base and Activator  
EPA Registration No. 8714-8  
Application Date: June 5, 2007  
Receipt Date: June 5, 2007

Dear Mr. Dawe:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable subject to the comment/condition listed below.

**Condition**

Correct the contact time under the "Disinfection" directions for use to read 5 hours. The proposed label states that: "Clidox-S solution can be used at the 1:18:1 dilution for 5 minutes . . ."

**General Comments**

A stamped copy of the labeling accepted with a condition is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please call Wanda Henson at (703) 308-6345.

Sincerely,

Emily H. Mitchell  
Product Manager - Team 32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

AUG 30 2007

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 8714-8

# CLIDOX-S® BASE

A CHLORINE DIOXIDE STERILANT  
FOR USE WITH CLIDOX-S® ACTIVATOR  
BACTERICIDAL - TUBERCULOCIDAL  
VIRUCIDAL - FUNGICIDAL

Sanitizing Level: CLIDOX-S® diluted 1:3:1 kills bacteria including dried spores of  
*Clostridium sporogenes* ATCC 3584 and *Bacillus subtilis* ATCC 19659 on environmental  
surfaces in 5 hours at 25°C.

Disinfecting Level: CLIDOX-S® diluted 1:18:1 kills vegetative bacteria including  
*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6339, and *Salmonella  
enterica* ATCC 10708, pathogenic fungi (*Trichophyton mentagrophytes* ATCC 9533),  
viruses\*, and *Mycobacterium bovis* ATCC 35763 (tuberculous bacteria) in 5 minutes at 20°C  
when used on pre-cleaned surfaces.

ACTIVE INGREDIENT	0.85%
Sodium Chloride	99.15%
OTHER INGREDIENTS	100.00%
Total	

**CAUTION:** See first aid and precautionary statements on second panel of label.  
\*This product completely inactivates Minute Virus of Mice (Parvovirus) ATCC-VR-1346  
when diluted 1:18:1 at 5 minutes at 21.5°C in the presence of 1% organic soil load. This  
product completely inactivates Herpes Simplex Virus type 2 (G-Strain), Polio Virus type  
1 (Brunhilde-VR-ATCC-58), and Human Immunodeficiency Virus Type 1 (REFStrain)  
(HIV-1) associated with AIDS when diluted 1:18:1 at 3 minutes at 20°C on pre-cleaned  
surfaces.

EPA REG. NO. 8714-8 EPA EST. NO. 8714-CT-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

FOR PROFESSIONAL USE ONLY

**Pharmacal**  
RESEARCH LABORATORIES, INC.

562 Captain Neville Drive, Waterbury, CT 06705

NET CONTENTS:

## PRECAUTIONARY STATEMENTS:

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION:** Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and  
water after handling and before eating, drinking, chewing gum, or using tobacco. Wash  
contaminated clothing before reuse.

## FIRST AID

**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 five minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

**If swallowed:**

- Call a 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.

**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.

## EMERGENCY NUMBER

Have the product container or label with you when calling a poison control center, doctor, or going for treatment. You may also contact CHEMTREC at 1-800-424-9300 for emergency medical information.

## PHYSICAL / CHEMICAL HAZARDS:

Long term exposure to this product will corrode carbon steel.  
Solution may bleach clothing. Use in well ventilated areas.

## Storage and Disposal

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

### PESTICIDE STORAGE:

Store in a cool dry place in original containers. Always replace cover.

### CONTAINER DISPOSAL:

Do not reuse empty container. Triple rinse empty container with water. Then offer for reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

For containers 1 gallon or less:

Do not reuse empty container. Puncture container and dispose of in sanitary landfill.

### PESTICIDE DISPOSAL:

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### DILUTIONS:

**STERILIZATION:** Articles should be thoroughly cleaned prior to treatment and immersed in CLIDOX-S® at a 1:3:1 dilution for 5 hours at 25°C. Mix with water as follows: Dilute 1 part CLIDOX-S® BASE into 3 parts tap water (20° - 30° C), then add 1 part CLIDOX-S® ACTIVATOR, making 5 parts total. CLIDOX-S® ACTIVATOR must be used with CLIDOX-S® BASE. Example: Pour 100 mL CLIDOX-S® BASE into 300 mL tap water, then add 100 mL CLIDOX-S® ACTIVATOR for a total of 500 mL. CLIDOX-S® solution will appear pale yellow. Once mixed, the solution should be used within 24 hours.

**DISINFECTION:** A 1:18:1 (1 part CLIDOX-S® BASE into 18 parts tap water, then add 1 part CLIDOX-S® ACTIVATOR) dilution may be used for disinfection at 20°C for 5 minutes. (Once mixed, the solution should be used within 14 days.)

**ROCKING DILUTION:** A 1:5:1 dilution is recommended for use in fogging/wet misting operations to sanitize surfaces as an adjunct to acceptable manual cleaning and sanitation of room surfaces. (1 part CLIDOX-S® BASE into 5 parts tap water, then add 1 part CLIDOX-S® ACTIVATOR) dilution may be used for disinfection at 20°C for 5 minutes. (Once mixed, the solution should be used within 14 days.)

### IMPORTANT:

Mix and let sit for 15 minutes before using.

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**DIRECTIONS FOR USE  
IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT  
IN A MANNER INCONSISTENT WITH ITS LABELING**

**STERILIZATION:**

CLIDOX-S® solution can be used for the sterilization of hard, nonporous, inanimate, environmental surfaces such as stainless steel, plastics (such as polycarbonate, polyvinyl chloride, polypropylene, and polystyrene), tile, and glass. For use in laboratory animal breeding and research animal quarters for controlling cross-contamination of microorganisms infectious to these animals and humans from treated surfaces.

Clean articles thoroughly prior to treatment and immersion in CLIDOX-S® at a 1:3:1 dilution for 5 hours at 25°C. Lumen of any hollow instrument must be flushed and filled. Asceptically transfer the treated articles to a sterile enclosed container for air drying. Judgment of the user according to individual techniques may require rinsing with sterile water as an alternative to air drying.

**DISINFECTION:**

CLIDOX-S® solution can be used at the 1:18:1 dilution for 5 hours at 20°C for the disinfection of hard, nonporous, inanimate, environmental surfaces such as stainless steel, plastics (such as polycarbonate, polyvinyl chloride, polypropylene, and polystyrene), tile, and glass. Instruments can also be decontaminated with this product prior to sterilization. For use in laboratory animal breeding and research animal quarters for controlling cross-contamination of microorganisms infectious to these animals and humans from treated surfaces. Also for use in laboratories, dental and medical offices, hospitals, and other health care facilities.

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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization.

Kills HIV-1 (AIDS virus) 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/body fluids, and in which the surfaces/objects likely to be soiled with blood/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 (AIDS VIRUS) OF  
SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUID:**

**Personal Protection:** Disposable latex or vinyl gloves, gowns, face masks, or eye coverings as appropriate must be worn during all cleaning of blood/body fluids and during decontamination procedures.

**Cleaning Procedures:** Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of this product.

**Contact Time:** HIV-1 (AIDS virus) is inactivated after a contact time of 2 minutes at 25°C (room temperature). Although efficacy at a 2-minute contact time has been shown to be adequate against HIV-1 (AIDS virus), this is not sufficient for the non-HIV organisms listed on the label. Therefore, a 5-minute contact time must be used for disinfection against all listed, non-HIV organisms.

**Disposal of Infectious Materials:** Blood/body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

**APPLICATION:**

Soaking is the best method of application; however, the solution may be applied by any convenient means (i.e., mop, cloth, sponge, spray, or fogged). Surface must remain wet for a minimum of five minutes.

**FOGGING DIRECTIONS:**

Use CLIDOX-S® solution at the 1:5:1 dilution for use in fogging/wet misting operations to sanitize surfaces as an adjunct to acceptable manual cleaning and disinfection of room surfaces. Area must be pre-cleaned with all gross soils removed prior to application. Pay close attention to safety issues and wear all appropriate personal protection equipment (gloves, face shield/eye goggles, lab coat, respirator suitable for acid mist, and booties). Please read Material Safety Data Sheets before using. Remove all animals and plants from area to be fogged. Remove or cover any equipment, light fixtures, or vents that should not be exposed to the CLIDOX-S®. Keep all people out of area while area is being treated. A turntable with an automatic timer provides the most uniform coverage. Follow specific directions from the fogger's manufacturer. Make sure enough chemical is placed in the reservoir to complete the job. Remember when determining the size of the room, multiply length x height x width. Place fogger in a central unobstructed location. Fog until the entire area is moist using an automatic fogger. Follow specific directions from the fogger's manufacturer. Rinse fogger with water following use. Wipe down treated surfaces with fresh, DI or RO water to remove any residue within an 8-hour period following application to reduce the possibility of corrosion.

**DECONTAMINATION OF INSTRUMENTS:** Dismantle equipment, if possible, and rinse free of heavy soil and gross debris. Moderate amounts of organic soil will not lower the efficiency of CLIDOX-S®. Soaking is the best method of application; however, the solution may be applied by any convenient means (i.e., cloth, sponge, or spray). Allow surfaces to remain thoroughly wet with solution for five minutes. Rinse with fresh, DI or RO water within 8-hours of application to reduce the possibility of corrosion.