



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

June 28, 2006

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC
SUBSTANCES

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

Subject: Pharmaceutical Research Laboratories, Inc.
 Clidox-S Base
 EPA Registration No. 8714-8
 Application Date: January 9, 2006
 Receipt Date: January 9, 2006

Dear Mr. Dawe:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is accepted with conditions.

Conditions

1. List the organisms designations (i.e., *Clostridium sporogenes* ATCC 3584, *Bacillus subtilis* ATCC 19659) on the second page of the label.
2. Change *Salmonella choleraesuis* to *Salmonella enterica* ATCC 10708.
3. The use dilution information has been inadvertently omitted from the virus section of the label. Please insert the following information under the virus section ". . .when diluted 1:18:1 at 3 minutes at 20°C on pre-cleaned surfaces."

General Comments

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

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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)

CLIDOX-S[®] BASE

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

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

Disinfecting Level: CLIDOX-S[®] diluted 1:18:1 kills vegetative bacteria including *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella choleraesuis*, pathogenic fungi (*Trichophyton mentagrophytes*), viruses*, and *Mycobacterium bovis* (tuberculosis bacteria) in 5 minutes at 20°C when used on precleaned surfaces.

ACTIVE INGREDIENT

Sodium Chlorite 0.85%

OTHER INGREDIENTS 99.15%

Total 100.00%

CAUTION: See first aid and precautionary statements on second panel of label.

*This product completely inactivates Herpes Simplex Virus type 2, Polio Virus type 1, and Human Immunodeficiency Virus type 1 (HIV-1) (associated with AIDS)

EPA Reg. No. 8714-8 EPA Est. No. 8714-CT-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

FOR PROFESSIONAL USE ONLY

NET CONTENTS:

Pharmal Research Laboratories, Inc.
562 Captain Neville Rd.
Waterbury, CT 06705

ACCEPTED
with COMMENTS
EPA Label Dated:

JUN 28 2006

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

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:	<ul style="list-style-type: none">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:	<ul style="list-style-type: none">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 doctorDo not give anything by mouth to an unconscious person.
If on skin or clothing:	<ul style="list-style-type: none">Take off contaminated clothingRinse 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 CH-MTREC at 1-800-424-9300 for emergency medical information.

PHYSICAL / CHEMICAL HAZARDS:

Long term exposure to this product will corrode carbon steel. Solutions 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 covers

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 mls. CLIDOX-S[®] BASE into 300 mls tap water, then add 100 mls. CLIDOX-S[®] ACTIVATOR for a total of 500 mls. 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.)

FOGGING 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 sanitization 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. Aseptically 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization.

Kills HIV-1 (AIDS virus) on precleaned 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 the 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 FLUIDS:

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 23°C (room temperature). Although efficacy at a 2-minute contact time has been shown to be adequate against HIV-1 (AIDS virus), this time 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 Material: 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[®] at the 1:5:1 dilution for use in fogging/wet misting operations to sanitize surfaces as an adjunct to acceptable manual cleaning and disinfecting of room surfaces. Area must be precleaned 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 surface 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.

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DIRECTIONS FOR USE

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IN A MANNER INCONSISTENT WITH ITS LABELING**

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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. Aseptically 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization.

Kills HIV-1 (AIDS virus) on precleaned 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 the transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

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Therefore, a 5-minute contact time must be used for disinfection against all listed, non-HIV organisms.

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

APPLICATION:

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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.

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CLIDOX-S[®] ACTIVATOR

A CHLORINE DIOXIDE STERILANT
FOR USE WITH CLIDOX-S[®] BASE
BACTERICIDAL - TUBERCULOCIDAL
VIRUCIDAL - FUNGICIDAL

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Contains 10% organic acid

CAUTION: See first aid and precautionary statements on second panel of label.

*This product completely inactivates Herpes Simplex Virus type 2, Polio Virus type 1, and Human Immunodeficiency Virus type 1 (HIV-1) (associated with AIDS)

EPA Reg. No. 8714-8 EPA Est. No. 8714-CT-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

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NET CONTENTS: _____

Pharmaceutical Research Laboratories, Inc.
562 Captain Neville Rd.
Waterbury, CT 06705

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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:	<ul style="list-style-type: none">• 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:	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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

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PHYSICAL / CHEMICAL HAZARDS:

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Storage and Disposal

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

PESTICIDE STORAGE:

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IMPORTANT:

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