

April 17, 2003

Frederick T. Smith
Pharmaceutical Research Laboratories, Inc.
33 Great Hill Road
Naugatuck, CT 06770

Subject: Clidox-S
EPA Registration No.8714-8
Application Date: February 3, 2003
Receipt Date: February 4, 2003

Dear Mr. Smith:

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

- addition of pump spray use

Condition

Remove the "etc." from the Decontamination of Instruments use directions. You may specifically refer to the methods of application in the following manner, i.e., mop, cloth, sponge, spray.

General Comments

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

CONCURRENCES

SYMBOL	7510C							
SURNAME	Mitchell							
DATE	4/17/03							

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

Sincerely,



*Robert S. Brennis
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)*

CLIDOX-S[®] BASE

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

Disinfecting Level: CLIDOX-S[®] diluted 1:18:1 disinfectant kills vegetative bacteria including *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella choleraesuis*, pathogenic fungi and viruses* in 5 minutes at 20°C, and *Mycobacterium bovis* 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 Type 2, Polio Virus type 1, and Human Immuno-deficiency Virus Type 1 (HIV-1)(associated with AIDS) when diluted 1:18:1 at 3 minutes at 20°C on precleaned surfaces.

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

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

FOR PROFESSIONAL USE ONLY

NET CONTENTS:

Pharmaceutical Research Laboratories, Inc.
33 Great Hill Rd., Naugatuck, CT 06770

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Harmful if swallowed, or absorbed through skin. 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	
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.	

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. <i>For containers 1 gallon or less:</i> 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.

PHYSICAL / CHEMICAL HAZARDS:

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

ACCEPTED
with COMMENTS
EPA Letter Dated:

APR 17 2003

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

3
2
6

DIRECTIONS FOR USE

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

CLIDOX-S® BASE is recommended for the decontamination of instruments prior to sterilization or high-level disinfection. It is recommended 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. For use in laboratories, dental and medical offices, hospitals, and other health care facilities. Also 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.

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 or high-level disinfection.

DILUTION: A 1:5:1 dilution may be used for hospital disinfection. Mix with water as follows: Dilute 1 part CLIDOX-S® BASE into 5 parts tap water (20°-30°C), then add 1 part CLIDOX-S® ACTIVATOR, making 7 parts total. CLIDOX-S® ACTIVATOR must be used with CLIDOX-S® BASE. Example: Dilute 100 mls. CLIDOX-S® BASE into 500 mls. tap water, then add 100 mls. CLIDOX-S® ACTIVATOR for a 700 mls. total. CLIDOX-S® solution will appear pale yellow. Once mixed, the solution should be used within 24 hours. 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.)

IMPORTANT: Mix and let sit for 15 minutes before using.

DECONTAMINATION OF INSTRUMENTS: Equipment should be dismantled, if possible, and rinsed 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 (mop, cloth, sponge, spray, etc.). The surface, instrument or apparatus should be thoroughly wet with solution. Lumen of any hollow instrument must be flushed with CLIDOX-S® solution and allowed to soak for 5 minutes. Rinsing is not necessary after treatment.

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 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).

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

4
8
6

CLIDOX-S[®] ACTIVATOR

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

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

Contains 10% organic acid.

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

*This product completely inactivates Herpes Simplex Type 2, Polio Virus type 1, and Human Immuno-deficiency Virus Type 1 (HIV-1)(associated with AIDS) when diluted 1:18:1 at 3 minutes at 20°C on precleaned surfaces.

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.
33 Great Hill Rd., Naugatuck, CT 06770

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Harmful if swallowed, or absorbed through skin. 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	
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.	

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.

PHYSICAL / CHEMICAL HAZARDS:

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

5
2
6

DIRECTIONS FOR USE

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

CLIDOX-S® ACTIVATOR is recommended for the decontamination of instruments prior to sterilization or high-level disinfection. It is recommended 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. For use in laboratories, dental and medical offices, hospitals, and other health care facilities. Also 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.

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 or high-level disinfection.

DILUTION: A 1:5:1 dilution may be used for hospital disinfection. Mix with water as follows: Dilute 1 part CLIDOX-S® BASE into 5 parts tap water (20°-30°C), then add 1 part CLIDOX®-S ACTIVATOR, making 7 parts total. CLIDOX®-S ACTIVATOR must be used with CLIDOX®-S BASE. Example: Dilute 100 mls. CLIDOX®-S BASE into 500 mls. tap water, then add 100 mls. CLIDOX®-S ACTIVATOR for a 700 mls. total. CLIDOX-S® solution will appear pale yellow. Once mixed, the solution should be used within 24 hours. 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.)

IMPORTANT: Mix and let sit for 15 minutes before using.

DECONTAMINATION OF INSTRUMENTS: Equipment should be dismantled, if possible, and rinsed 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 (mop, cloth, sponge, spray, etc.). The surface, instrument or apparatus should be thoroughly wet with solution. Lumen of any hollow instrument must be flushed with CLIDOX-S® solution and allowed to soak for 5 minutes. Rinsing is not necessary after treatment.

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 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).

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

6
2
6