

8714-8

03-17-2010

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



Office of Pesticide Programs

MAR 17 2010

Cinda Bell
Regulatory Specialist
Pharmaceutical Research Laboratories, Inc.
c/o SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

FILE COPY

Subject: Clidox-S Base
EPA Reg. No. 8714-8
Application Dated: February 17, 2010
Receipt Date: February 26, 2010

Dear Ms. Bell:

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9 is acceptable.

Proposed Notification:

- Revised Storage and Disposal Statement per PR Notice 2007-4

Comments:

Based on a review of the material submitted, the following comments apply:

This application for notification to revise the storage and disposal statement, as referenced above, is acceptable. A copy has been placed in our records for future reference.

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

Sincerely,

Wanda Y. Henson
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)



United States
Environmental Protection Agency
 Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 8714-8	2. EPA Product Manager W. Henson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Clidox-S	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Pharmaceutical Research Laboratories, Inc. 562 Captain Neville Drive Waterbury, CT 06705 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. 4 gal	No. Per Container 4
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 gal, 4/1 gal, 5 gal, 30 gal, 55 gal	5. Location of Label Directions <input checked="" type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other silkscreened	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Cinda L. Bell	Title Agent (SciReg, Inc.)	Telephone No. (Include Area Code) 703/494-6500
Certification I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		3. Date Application Received (Stamped)
2. Signature <i>Cinda L. Bell</i>	3. Title Agent (SciReg, Inc.)	
4. Typed Name Cinda L. Bell	5. Date 2/23/10	

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SciReg, Inc.
Science and Regulatory Consultants

February 23, 2010

Ms. Sherada Hobgood
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202


Re: Notification consistent with PR Notice 2007-4
- Clidox-S (EPA Reg. No. 8714-8)

Dear Ms. Hobgood:

On behalf of Pharmacal Research Laboratories, Inc. (PRL), SciReg, Inc. is submitting a notification consistent with PR Notice 2007-4 to update PRL's Container Handling text for Clidox-S (EPA Reg. No. 8714-8). One copy of the label, with the changes clearly marked, is included.

Should you have any questions, please let us know.

Sincerely,



Cinda L. Bell
Regulatory Specialist

Enclosures

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* 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 6538, and *Salmonella enterica* ATCC 10708, pathogenic fungi (*Trichophyton mentagrophytes* ATCC 9533), viruses*, and *Mycobacterium bovis* ATCC 35743 (tuberculosis bacteria) in 5 minutes at 20°C when used on pre-cleaned 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 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 (RFStrain) (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

pharmacial
RESEARCH LABORATORIES, INC.

562 Captain Neville Drive, Waterbury, CT 06705

Net Contents:

Batch:

NOTIFICATION
Date Reviewed: 3/17/10
Reviewed By: W. Hensley

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 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.

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 covers.

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

CONTAINER HANDLING (For containers equal to or less than 5 gallons): Non-refillable container. Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state. Triple rinse container (or equivalent) 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 ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

CONTAINER HANDLING (For containers greater than 5 gallons): Non-refillable container. Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ 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. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

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 sanitization 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 minutes 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 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:**

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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 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® 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 disinfecting 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, faceshield/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.