



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

August 15, 2024

Frederick T. Smith
Agent
SciReg, Inc. for
Pharmaceutical Research Laboratories, Inc.
Electronic Transmittal: fsmith@scireg.com

Subject: PRIA Label Amendment – Label Amendment to Extend Storage Timeframe
Product Name: CLIDOX-S BASE
EPA Registration Number: 8714-8
Application Date: 01/24/2023
Action Case Code Number: 00427545

Dear Frederick T. Smith:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Jack Hall via email at hall.john.j@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "DF", with a long horizontal stroke extending to the right.

Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

ACCEPTED

08/15/2024

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

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.

*This product completely inactivates Minute Virus (Parvovirus) of Mice ATCC-VR-1346 when diluted 1:18:1 in 5 minutes at 21.5°C on pre-cleaned surfaces. 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 in 3 minutes at 20°C on pre-cleaned surfaces.

This product also completely inactivates Murine Norovirus MNV-1.CW1 when diluted at 1:4:1 in 5 minutes at 20°C 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.**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 Dr.
Waterbury, CT 06705

NET CONTENTS:

BATCH:

Manufactured on:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves (such as, or made out of, PVC, neoprene, nitrile rubber, or any waterproof material).

First Aid	
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.
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 to an unconscious person.
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.	

Mixers, loaders, applicators and other handlers must wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves (such as, or made out of, PVC, neoprene, nitrile rubber, or any waterproof material).

Follow manufacturer's instruction for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

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

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, use the solution 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, use the solution within 14 days.

MURINE NOROVIRUS MNV-1.CW1: A 1:4:1 dilution is required for the deactivation of Murine Norovirus MNV-1.CW1 (1 part CLIDOX-S BASE into 4 parts tap water, then add 1 part CLIDOX-S ACTIVATOR). Dilution may be used for disinfection at 20°C for 5 minutes on pre-cleaned surfaces. Once mixed, use the solution within 24 hours.

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

DIRECTIONS FOR USE

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

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.

User Safety Instructions

- Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

STERILIZATION: CLIDOX-S® solution can be used for the sterilization of hard, nonporous, inanimate, environmental surfaces such as stainless steel, plastics (such as: polycarbonate, polyvinylchloride, 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.

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).

FOR DISINFECTING HARD, NON-POROUS SURFACES AGAINST MURINE NOROVIRUS MNV-1.CW1: CLIDOX-S® solution can be used at the 1: 4:1 dilution for 5 minutes at 20°C on pre-cleaned surfaces for the deactivation of Murine Norovirus MNV-1.CW1 on hard, nonporous, inanimate, environmental surfaces such as stainless steel, plastics (such as: polycarbonate, polyvinyl chloride, polypropylene, and polystyrene), glazed tile, and glass.

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 3 minutes at 23°C (room temperature). Although efficacy at a 3-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, or spray). Surface must remain wet for a minimum of five minutes.

DISINFECTION OF INSTRUMENTS: Dismantle equipment and pre-clean surfaces to be disinfected. 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.

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. This product is stable for 2 years following the date of manufacture.

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 $\frac{1}{4}$ 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 $\frac{1}{4}$ 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.