

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

7M32

8714-8

9/17/98

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Frederick T. Smith, Agent
 Pharmacal Research Laboratories, Inc.
 % SRA International, Inc.
 1850 M Street NW, Suite 290
 Washington, DC 20036

SEP 17 1998

Dear Mr. Smith:

Subject: Clidox-S (EPA Reg. No. 8714-8)
 Confidential Statements of Formula and Label Amendments
 Correspondence Dated August 3, 1998

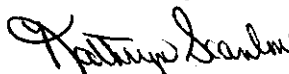
The basic and alternate Confidential Statements of Formula (CSF) are acceptable for the above product and supersede all previous CSFs for the product.

On the base label the term "Ingredient Statement" is not needed and should be deleted from the label.

On the activator label the entire ingredient statement should be deleted and replaced with the statement "contains organic acid 10%". One product may not have two different ingredient statements. There is only one active ingredient in this product "sodium chlorite 0.85%".

Stamped copies of the labels are enclosed for your records. Should you have any questions or concerns, please call (703) 308-6418.

Sincerely Yours,



Kathryn Scanlon
 Product Reviewer
 Team 32
 Regulatory Management Branch II
 Antimicrobial Division (7504C)

7510W:K.Scanlon:ks:09/15/98:CLIDOX S1.LTR

CONCURRENCES

SYMBOL ▶	7510W							
SURNAME ▶	K. Scanlon							
DATE ▶	Sep 15, 1998							

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 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.

CLIDOX-S® is a hospital disinfectant suitable for use in animal breeding quarters.

INGREDIENT STATEMENT

ACTIVE INGREDIENT

Sodium Chlorite0.85%

INERT INGREDIENTS99.15%

Total.....100.00%

CAUTION: See back panel for precautionary statements.

*This product completely inactivates Herpes Simplex Type 2, Polio Virus Type 1, and Human Immunodeficiency 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

CLIDOX-S® BASE is recommended for the decontamination of instruments prior to sterilization or high level disinfection. It is recommended for the disinfection of surfaces such as stainless steel, aluminum, plastics (such as polycarbonate, polyvinyl chloride, polypropylene, 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.

CAUTION

KEEP OUT OF REACH OF CHILDREN
FOR PROFESSIONAL USE ONLY

NET CONTENTS:

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 17 1990

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

8714-8

DIRECTIONS FOR USE

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

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. ACTIVATOR must be used with CLIDOX-S® BASE. Example: Dilute 100 mls. BASE into 500 mls. tap water, then add 100 mls. ACTIVATOR for a 700ml. total. CLIDOX-S® solution may appear clear or 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 (moist cloth, sponge, etc.). The surface, instrument or apparatus should be thoroughly wet with solution. Lumen of an 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 disinfectant.

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.

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**PRECAUTIONARY STATEMENT:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Harmful if swallowed. Do not get in eyes, on skin, or on clothing.

FIRST AID: *If in eyes: Flush with plenty of water. Get medical attention. If swallowed: Drink promptly a large quantity of water. Get medical attention. If on skin: Wash with plenty of soap and water. Get medical attention. Contaminated clothing should be washed before reuse.*

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 or high level disinfection.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Store in cool dry place in the original containers. Always replace covers. Keep upright. Do not reuse empty container. Triple rinse empty container with water. Then offer for reconditioning or puncture and dispose of in sanitary landfill, or by other procedures approved by State and local authorities.

Physical / Chemical Hazards

Long-term exposure will corrode carbon steel. Solution may bleach clothing. Use in ventilated areas.

For chemical emergency, call CHEMTREC at 1-800-424-9300

pharmacial
RESEARCH LABORATORIES, INC.
33 Great Hill Rd. Naugatuck, Ct. 06770

animal environmental control products

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CLIDOX-S[®] ACTIVATOR

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BACTERICIDAL-TUBERCULOCIDAL
VIRUCIDAL - FUNGICIDAL

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CLIDOX-S[®] is a hospital disinfectant suitable for use in animal breeding quarters.

INGREDIENT STATEMENT

ACTIVE INGREDIENT

Hydroxyacetic Acid 10.0 %

OR

Lactic Acid .. 10.0 %

INERT INGREDIENTS ... 90.0 %

Total 100.0 %

Contains Organic Acid
CAUTION: See back panel for precautionary statements.

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EPA REG. NO. 8714-8

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