

JUL 25 1990

Pharmaceutical Research Labs, Inc.  
33 Great Hill Road  
Meyersrock, CT 06770

Gentlemen:

Subject: Clidox-g Base  
MPA Registration No. 8714-8  
Your Submission Dated May 16, 1990

This is in response to your resubmission regarding your request to amend the registration of the subject product to include an additional use dilution and revised labeling.

The amendment referred to above is acceptable provided that you:

1. Make the following labeling revisions before you release the product for shipment bearing the amended labeling.
  - a. Include MPA Registration No. 8714-8 on the base label.
  - b. Under "Disinfecting Level," revise ". . . . Harpes Simplex 2 and Polio Virus 1 . . ." to read ". . . . Harpes Simplex, Type 2 and Polio Virus, Type 1 . . ." (Note the inclusion of the word "Type." Refer to comment 3 of our previous letter in this regard.)
2. Submit the finished printed labeling for inclusion in the product files.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the edited label is enclosed for your records.

51488-1-Douglas C. Diskin/KRCCO:7/20/90:Kyrone/kide  
CONCURRENCES

SYMBOL	SUBSTANCE	DATE						

-3-

Note that the labeling for the activator (nonpesticidal) product has been included in the files for the subject product.

If you have any questions in this regard, please contact Ms. Ruth Douglas at (703) 557-3642.

Sincerely yours,



Walter C. Francis  
Acting Product Manager (32)  
Antimicrobial Program Branch  
Registration Division (N7505C)

Enclosure

No. Contents 18 U.S. Gallon (g)  
**CLIDOX-S BASE**

FOR USE WITH CLIDOX - S ACTIVATOR 1:5:1

STERILANT-BACTERICIDAL-TUBERCULOCIDAL  
VIRUCIDAL-FUNGICIDAL

Sterilizing Level: CLIDOX - S diluted 1:5:1 kills bacteria including dried spores of *C. sporogenes* and *B. subtilis* on environmental surfaces in 6 hours at 20°C. Completely inactivates the HIV-1 (AIDS virus) and HBV (Hepatitis B virus) when used in accordance with the direction for sterilization.

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.

Active: Sodium Chlorite.....0.85%  
Inert Ingredients:.....99.15%  
TOTAL.....100.00%

Keep Out of Reach of Children

CAUTION: See back panel for precautionary statements.

CLIDOX - S  
STERILANT (1:5:1) and DISINFECTANT (1:18:1)  
FOR ANIMAL BREEDING QUARTERS

*EPA Reg. No. 8714-8*  
*EPA Est. No. -----*

APPROVED  
FOR DISINFECTANT  
USE, Letter Dated

JUL 25 1980

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

\*This product kills Herpes 1) when diluted 1:18:1 at 20°C on precleaned surfaces.

CLIDOX - S BASE

CLIDOX - S is used for disinfection of instruments and stainless steel (such as: polychloride, polytile and glass dental and medical and other health care) for use in laboratories and research areas cross-contaminated with infectious to prevent spread from treated surfaces.

**DISINFECTION:** 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 sprayed or wiped on by any convenient means (mop, cloth, sponge, etc.). The surface, instrument or apparatus should be thoroughly wet with solution. Lumen of any hollow instrument must be flushed and apply for up to 5 minutes. Rinsing is not necessary after treatment.

**STERILIZATION:** Articles should be thoroughly cleaned prior to treatment and immersed in CLIDOX - S at a 1:5:1 dilution for 6 hours. Lumen of any hollow instrument must be flushed and filled. Aseptic transfer of the treated articles to a sterile enclosed container for air drying is recommended. Judgement of the user according to individual techniques may require rinsing with sterile water as an alternative to air drying.

**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. Avoid alcohol. Get medical attention. If on skin: Wash with plenty of soap and water. Get medical attention.

#### **STORAGE AND DISPOSAL**

Do not contaminate water feed by storage or disposal.

Store in cool, dry place in original containers. Keep upright. Containers thoroughly cleaned and discard in trash. Do not reuse containers.

#### **Physical/Chemical HAZARD**

Long exposure will corrode steel. Solution may be used in ventilated areas.