

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

143 PM
31

JUL 20 1989

Calco, Inc.
909 Parkside Drive
Silver Spring, MD 20910

BEST AVAILABLE COPY

Attention: Mr. W. S. S. S. S.

Gentlemen:

Subject: Calco, Inc.
EPA Registration No. 55195-2
Your Submission Dated June 13, 1989

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
 - a. Review the label and document "Label Requirements for Antimicrobial Products Used on Hard Surfaces Against HIV-1 (AIDS Virus)" for EPA's current labeling policy for efficacy claims. Your labeling must be revised in accordance with the requirements outlined in this policy notice.
 - b. Revised the label statement to read:

See right panel for additional precautionary statements.
 - c. Revise the statement "Additional precautions and First Aid" to read:

Precautionary Statements
Hazards to Humans and Domestic Animals

- d. Revise the "First Aid" heading to read:

Statement of Practical Treatment

54776:I:DeLaney:LL-16:KENCO:07/12/89:08/21/89:aw:gf:vo:de:dg

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

-2-

2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

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

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 557-6982.

Sincerely yours,

John H. Lee
Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosures

ColdCide-10

For Use and Reuse
For Up to 30 Days
In a Manual Bucket System.

- * Dilute for disinfection
- * Corrosion inhibitor
- * Stable, low pH formula
- * Dilute for sterilization
- * No activator required

Sporicidal
Virucidal*
Tuberculocidal

Fungicidal
Bactericidal
Pseudomonacidal

Active ingredients	
Glutaraldehyde	10.0%
O-Phenylphenol	0.5%
P-Tertiary Amylphenol	0.1%
Inert ingredients	89.4%
Total	100.00%

Product No.

MX-5332

EXPIRATION DATE:

2 YEARS AFTER

MANUFACTURING DATE

ACCEPTED FOR DISINFECTION
COMMITTEE THOROUGHLY AFTER HANDLING.

JUL 20 1988

Keep out of reach of children.

DANGER: See additional precautions
and first aid on right panel.

Contents 25.6 fluid oz.
Made in U.S.A.
Production lot # is stamped
on bottom of container

Patented
E.P.A. Reg. No. 55195-2
E.P.A. Est. No. 46781-CO-1

Before using in disinfecting solution. Prepare a 1:20 dilution (4 gallons) by contents of this container (25.6 fl. oz.) into an empty five-gallon container and fill to 4-gallon marker. Completely immerse instruments in disinfecting solution for 10 minutes at room temperature (20°C/68°F or higher). At a 1:20 dilution, ColdCide-10 kills *Salmonella*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Trichophyton mentagrophytes*, *Neoformens*, and *Candida albicans*. *Mycobacterium tuberculosis* is completely inactivated at 20°C/68°F or higher in 10 minutes. Completely inactivates the following: Herpes simplex virus 1 & 2 and Influenza A, HK, and inactivated at 20°C/68°F. Coxsackievirus B5a, Adenovirus-2, Poliovirus-1&2, Rotavirus SA, Cytomegalovirus, Respiratory Syncytial Virus and Vaccinia virus.

ColdCide-10 completely inactivates the HIV-1 (AIDS virus) on hard, non-porous surfaces. A moderate amount of organic soil (5% blood serum) at a contact time of 30 seconds at 20-25°C after reuse of a 1:20 diluted solution for 30 days in manual systems. Although efficacy at a 30 second contact time has been shown to be adequate for HIV-1, this time would not be sufficient for other organisms. Use a 10-minute contact time for disinfection against all of the organisms claimed.

Remove instruments using aseptic technique, rinse with potable water, and dry. Instruments may be used and reused for up to 30 days.

STERILIZATION: All articles and surfaces to be sterilized must be thoroughly cleaned before placing in sterilizing solution. Prepare a 1:5 dilution by pouring entire contents of this container (25.6 fl. oz.) into an empty gallon container and filling with tap water. Completely immerse instruments in sterilizing solution for 6 hours at room temperature (20°C/68°F or higher). Remove instruments using aseptic technique, rinse with sterile water and dry. This solution may be reused for up to 30 days. A 1:20 dilution may be used for sterilization with 12 hours.

ADDITIONAL PRECAUTIONS AND FIRST AID:

DANGER: Corrosive. Causes eye damage. Do not get in eyes, on skin or on clothing. Wear safety glasses and rubber gloves when handling. Harmful if swallowed. Avoid contamination. Reuse of unwashed disinfectant-soaked gloves. Avoid prolonged inhalation.

FIRST AID: If in eyes, immediately flush with water for at least 15 minutes. Get medical attention. If on skin, wash thoroughly with water. Wash contaminated clothing before reuse.

COMMITTEE THOROUGHLY AFTER HANDLING.

Letter Dated:

STORAGE AND DISPOSAL:

Store in cool, well ventilated area. Unused product may be discarded by pouring into a large quantity of water. Rinse empty container thoroughly and discard. For use in hospitals, medical offices, dental offices, veterinary laboratories, convalescent homes and other health care facilities.

Especially recommended for sterilization or disinfection of Medical Instruments used in Anesthesiology, Endoscopy, Respiratory therapy, Surgery and Urology. Dental Instruments as Handpieces, Hemostats, Elevators, Diamond stones, Mirrors, Gauges and Burrs, Trays, Exam tables, Sharp instruments, Forceps, Sinks, Cages, Plastic objects, Aluminum objects, Thermometers, and Endoscopes.

Manufactured by:

ColdCide, Inc., Silver Spring, Md.