

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 3 1995

ColCide, Inc.
11500 West Hill Drive
Rockville, MD 20852

Attention: Kyle H. Sibinovic, Ph.D.
Agent

Subject: ColdCide-2
EPA Registration No. 55195-1
MOU Compliance Amendment dated November 2, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you make the labeling change listed below before you release the product for shipping bearing the amended label.

1. Revise the statement: "This product is not to be used as a terminal sterilant/disinfectant..." to read, "This product is not to be used as a terminal sterilant/high level disinfectant..."

A stamped copy of the labeling is enclosed for your records. Submit 5 copies of the final label prior to releasing the product for marketing.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely yours,



Walter C. Francis
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

COLDCIDE-2

GENERAL PURPOSE DISINFECTING AND CLEANING CONCENTRATE SOLUTION
 GLUTARALDEHYDE/COMPATIBLE DUAL PHENOLICS
 SURFACE DISINFECTANT/CLEANER - IMMERSION - PRE-CLEANER/HOLDING -ULTRASONIC SOLUTION
 FOR USE AND REUSE FOR UP TO 30 DAYS IN A MANUAL BUCKET SYSTEM

*DILUTE FOR DISINFECTION *DILUTE FOR PRE-CLEANING
 *NO ACTIVATOR REQUIRED
 *STABLE, LOW PH FORMULA

BACTERICIDAL	TUBERCULOCIDAL
PSEUDOMONICIDAL	VIRUCIDAL* FUNGICIDAL

ACTIVE INGREDIENTS:	
GLUTARALDEHYDE	2.00%
O-PHENYLPHENOL	0.10%
P-TERTIARY AMYLPHENOL	0.02%
INERT INGREDIENTS	<u>97.88%</u>
	100.00%

KEEP OUT OF REACH OF CHILDREN
 DANGER
 See left panel for additional precautionary statement.

NET CONTENTS: 1 GALLON

E.P.A. REG. NO. 55195-1

E.P.A. EST.NO. 46781-CO-1

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:

JAN 3 1995

COLDCIDE-2
 Trademark of

COLCIDE INC.
 11500 W. HILL DRIVE
 ROCKVILLE, MD 20852

Patented

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

55195-1

This product is not to be used as a terminal sterilant/disinfection 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.

PRODUCTION LOT NUMBER IS STAMPED ON THE BOTTOM OF CONTAINER.

EXPIRATION DATE: 2 YEARS AFTER MANUFACTURING DATE.

DIRECTIONS :

It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling.

For Use In Non-Critical Areas as a General Purpose Disinfectant in hospitals, medical offices, dental offices, veterinary laboratories, convalescent care centers and other health care facilities. ColdCide-2 is designed for repeated use in manual (bucket and tray) systems. Not to be used in metal trays, or as an overnight holding solution.

Disinfection: All articles and surfaces to be disinfected must be thoroughly cleaned and rough dried before placing in disinfecting solution. Mix one part of ColdCide-2 with one (1) part of water for a 1:2 dilution (1.0% principal active ingredient). Completely immerse instruments in disinfecting solution for 10 minutes at room temperature (20 C/68 F) or higher. ColdCide-2 may be applied with a wipe to disinfect medical equipment surfaces as well, leaving the surface wet 10 minutes or longer. At this dilution (1:2), ColdCide-2 kills Salmonella choleraesuis, Staphylococcus aureus, Pseudomonas aeruginosa, Trichophyton mentagrophytes, Cryptococcus neoformans, and Candida albicans. Mycobacterium tuberculosis is completely inactivated in 10 minutes at 20 C/68 F) or higher. The listed viruses* are completely inactivated within 2 minutes at 20 C/68 F: Herpes simplex 1 & 2, Influenza A₂HK, Coxsackie B₅, Poliovirus 1 & 2, Adenovirus-2, Rhinovirus, Rotavirus SA-11, Cytomegalovirus, Respiratory Syncytial Virus, and Vaccinia Virus.

ColdCide-2 completely inactivates the HIV-1 (AIDS virus) on hard, non-porous surfaces in the presence of a moderate amount of organic soil (5% blood serum) at a contact time of 30 seconds at room temperature (20-25 C) after reuse of a 1:4 diluted solution for 30 days in a manual (bucket or Tray) systems. Although efficacy at a 30-second contact time has been shown to be adequate against HIV-1, this time and concentration would not be sufficient for other organisms. Use a 30 minute contact time for disinfection against all of the organisms claimed.

Remove such non-critical instruments using aseptic technique, rinse with potable water, and dry. This solution may be used and reused for up to 30 days in a manual bucket system.

BEST AVAILABLE COPY

USE RECOMMENDATIONS:

Especially recommended for pre-cleaning and disinfection of non-critical medical, dental and veterinary equipment. ColdCide-2 will effectively pre-clean and disinfect, when used as directed, such items as counter tops, exam tables, trays, cages, plastic objects, rubber objects, aluminum objects, oxygen hoods, anesthesia and respiratory monitoring equipment surfaces, lights and other such non-critical equipment.

ColdCide-2 is recommended for the pre-cleaning and cleaning of instruments and for the disinfection of non-critical instruments.

For use as an ultrasonic cleaning solution:

Thoroughly rinse objects under cool running water to remove gross debris. Using a 1:4 dilution of ColdCide-2 (1 part of ColdCide-2 to 3 parts of water), immerse instruments into solution and activate ultrasonic unit for ten (10) minutes or longer if necessary. Remove and rinse. Change solution as needed, but at least daily.

For use as an ultrasonic disinfectant:

Immerse pre-cleaned objects into ColdCide-2 diluted 1:2 (1 part ColdCide-2 into 1 part water) and activate ultrasonic unit for ten (10) minutes or longer. Remove and rinse and dry prior to use. For disinfection, when Mycobacterium tuberculosis is suspected, the unit should be run for 10 minutes.

For use as a terminal disinfectant for non-critical instruments:

Instruments must be thoroughly cleaned to remove excess organic debris, rinsed, and rough dried. (Be sure to clean and rinse the lumens of hollow instruments before filling with solution or before immersion.) Immerse instruments into ColdCide-2 diluted 1:2 (1 part ColdCide-2 into 1 part water) and allow to remain submerged for ten (10) minutes or longer at room temperature (20 C/68 F). Remove, rinse and dry prior to use. Change solution as needed, but in any case in not more than 30 days.

For use as a manual pre-cleaner, cleaner for instruments:

Pre-clean instruments by placing in a tray of ColdCide-2 diluted 1:4 (1 part of ColdCide-2 into 3 parts water) for at least ten (10) minutes. If tray is used for several instruments, allow to remain at room temperature (20 C/68 F) for at least ten (10) minutes after the last addition is made and, then, rinse under cool running water before cleaning. Clean instruments as usual.

For manual cleaning, rinse dirty, contaminated instruments under cool running tap water to remove gross debris. Place instruments into a solution of ColdCide-2 diluted 1:4 (1 part ColdCide-2 into 3 parts water). Allow to soak for ten (10) minutes or longer before scrubbing using a stiff bristle brush. (Keep instruments submerged while being scrubbed.) Rinse thoroughly. Change solution as needed.

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KILLS HIV 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 or body fluids, and in which the surfaces/objects likely to be soiled with blood or 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 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS: Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of ColdCide-2 diluted 1:2 (1 part ColdCide-2 into 1 part water). Contact time: While the HIV-1 virus is inactivated in 30 seconds, use the recommended contact time for disinfection of other organisms on this label. Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be autoclaved and disposed of in accordance with local regulation for infectious disposal.

STORAGE AND DISPOSAL:

Store in cool, well ventilated area. Unused product may be discarded by pouring down drain and flushing with large quantity of water. Rinse empty container thoroughly and discard in trash.

PRECAUTIONARY STATEMENTS:

Hazard to Humans and Domestic Animals

DANGER: CORROSIVE. Causes eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear safety glasses and rubber gloves when handling. Harmful if swallowed. Avoid contamination of food. Avoid reuse of unwashed, disinfectant-soaked gloves. Avoid inhalation - use in ventilated area.

STATEMENT OF PRACTICAL TREATMENT: In case of eye contact, flush with water immediately for at least 15 minutes. Seek medical attention. If on skin, wash with water thoroughly. Seek medical attention. If swallowed, drink at least two glasses of water. Do not induce vomiting. Call for medical attention immediately. Wash contaminated clothing before reuse.

WASH THOROUGHLY AFTER HANDLING.

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