

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

October 1994

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

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

Subject: ColCide-0.25% Disinfectant Spray
EPA Registration No. 55195-3
MOU Compliance Amendment dated October 31, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

The labeling submitted in compliance with PR Notice 94-4 is acceptable. A stamped copy is enclosed for your records.

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							

DRAFT LABEL

COLDCIDE-0.25% DISINFECTANT SPRAY

10-31-94

COLDCIDE - 0.25% DISINFECTANT SPRAY

Glutaraldehyde / Compatible Dual Phenolics

Virucidal*	ACTIVE INGREDIENTS:	
Fungicidal	Giutaraldehyde	0.2500%
Bactericidal	O-Phenylphenol	0.0125%
Tuberculocidal	P-Tertiary Amylphenol	0.0025%
Pseudomonacidal	INERT INGREDIENTS	99.7350%
	TOTAL	100.0000%

REFILL AVAILABLE

CAUTION: KEEP OUT OF REACH OF CHILDREN
See back panel for additional precautionary statements.

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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 or high level disinfection.

CONTENTS: 20 FL. OZ. (591 ml)
Reorder MX-5350^{1/2}

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 16 1994

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
amended by the FIFRA Reauthorization Act of 1990,
this product is registered under EPA Reg. No.

55195-3

DIRECTIONS FOR USE:

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

For use in non-critical care areas as a general disinfectant spray on hard surfaces.

Disinfection: This product is to be used for the disinfection of hard, inanimate surfaces such as counter tops, tables, cages, plastic or other similar, hard surfaces.

This product is to be used as is, undiluted. Contact time is 10 minutes at room temperature (20 C/68 F) or higher) for bactericidal activity, or 2 minutes for virucidal activity.

ColdCide-0.25% Disinfectant Spray kills Salmonella choleraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa, and Trichophyton mentagrophytes in 10 minutes at 20 C/68 F or higher. Mycobacterium tuberculosis is completely inactivated in 15 minutes at room temperature (25 C or higher). Herpes simplex virus 1 & 2 and Influenza A₂HK are inactivated in 30 seconds, and the listed viruses* within 2 minutes at 20 C/68 F or higher: Coxsackie B5a, Adenovirus-2 virus, Poliovirus 1 & 2, Rotavirus SA-11, Rhinovirus, Vaccinia virus, Cytomegalovirus and Respiratory Syncytial Virus. **ColdCide-0.25% Disinfectant Spray** inactivates the HIV-1 (AIDS virus) on hard, non-porous surfaces in 30 seconds at room temperature (20-25 C). See accompanying technical literature on HIV-1 (AIDS virus).
Spray surfaces and allow to air dry.

PRECAUTIONARY STATEMENTS:

Hazard to Humans and Domestic Animals.

CAUTION: May be irritating to eyes. Do not get in eyes, on skin or on clothing. Wear safety glasses and rubber gloves when handling. Repeated dermal contact may result in dermal sensitization in some individuals. Harmful if swallowed. Avoid contamination of food. Avoid reuse of unwashed, disinfectant soaked gloves. Avoid prolonged inhalation.

STATEMENT OF PRACTICAL TREATMENT: 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.

WASH THOROUGHLY AFTER HANDLING.

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.

Patented

Manufactured in U.S.A. by Metrex Research, Inc.
Parker, CO 80134
1-800-841-1428

EPA Reg. No. 55195-3

EPA Est. No. 46781-CO-1

Expiration Date: 2 Years After Date Manufactured

Production Lot No. is stamped on bottom of container.

HIV-1 (AIDS VIRUS) INFORMATION
THE ACTIVITY OF COLDCIDE-0.25% DISINFECTANT SPRAY
(EPA REG. #55195-3_
AGAINST THE HIV-1 (AIDS VIRUS)

ColdCide-0.25% Disinfectant Spray 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). Although efficacy at a 30 second contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 15-minute contact time for disinfection against all of the organisms claimed.

ColdCide-0.25% Disinfectant Spray kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare 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 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of **ColdCide-0.25% Disinfectant Spray**.

Contact Time: Leave surfaces wet for 30 seconds. This contact time will not control other common types of viruses or bacteria.

Disposal of Infectious Materials: Materials that may contain blood or other body fluids should be autoclaved and disposed of according to Federal, State and Local regulations for infectious waste disposal.

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11500 W. Hill Dr.
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1-301-468-1668