

MAY 18 1992
MAY 10 1992

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

Attn: Brad E. James

Subject: ColdCide-10
EPA Registration No. 55195-2
Amendment dated May 14, 1992

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, and the stipulation dated May 14, 1992 in U.S.D.C. Civil Action 92-B-922 was granted on May 15, 1992. Our approval of the amendment is conditioned upon the following:

1) You must submit 2 copies of this product's Confidential Statement of Formula properly executed on EPA Form No. 8570-4 within 21 days of the date of this letter.

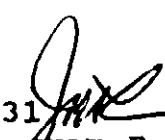
2) You must submit 5 copies of legible paper labels.

3) You must submit acceptable efficacy data in accordance with paragraph 5 of the stipulation.

Your continued release for shipment of the product bearing the amended labeling will be construed as constituting acceptance of these conditions.

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

Sincerely,

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

Enclosure

ENLARGED



OVERLINE
ARTWORK APPROVAL

Sterilizing and Disinfecting Solution
Glutaraldehyde/Compatible Dual Phenolics

ColdSpor

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



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

Sporicidal Virucidal* Fungicidal
Tuberculocidal Bactericidal Pseudomonicidal

Active ingredients		Product No.
Glutaraldehyde	10.0%	MX-5310
0 - Phenylphenol	0.5%	
2 - Tertiary Amphenol	0.1%	
by ingredients	85.4%	
Total	100.0%	
		EXPIRATION DATE: 2 YEARS AFTER MANUFACTURING DATE

KEEP OUT OF REACH OF CHILDREN
ANGER

See back panel for additional precautionary statements.

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. Thoroughly wash exposed areas of body. Avoid contact with food. Avoid fumes of unventilated, chlorinated, sealed systems. Avoid inhalation — use in well-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 help immediately. With contaminated clothing before reuse.
WASH THOROUGHLY AFTER HANDLING.
Net Content: 8.4 oz. EPA Reg. No. 55185-2-65781 EPA Est. No. 45781-00-1

DIRECTIONS FOR USE: It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling.
For use in hospitals, medical offices, dental offices, veterinary laboratories, convalescent care centers and other health care facilities. ColdSpor is designed for repeated use in manual (bucket and tray) systems.
DISINFECTION: All articles to be disinfected must be thoroughly cleaned and rough dried before placing in disinfecting solution. Mix one part of ColdSpor with nineteen parts of water for a 1:20 dilution (0.5% principal active ingredient), or prepare one gallon of a 1:20 dilution by pouring entire contents of the 8.4 oz. container into an empty one gallon container and filling with tap water. Completely immerse instruments in disinfecting solution for 10 minutes at room temperature (20°C/68°F) or higher. At this dilution (1:20), ColdSpor kills *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Trichophyton mentagrophytes*, *Cryptococcus neoformans*, and *Candida albicans*. *Mycobacterium tuberculosis* is completely inactivated in 10 minutes at room temperature (20°C/68°F) or higher.
The listed viruses* are completely inactivated within 2 minutes at 20°C/68°F: Herpes simplex virus 1 & 2, Influenza A₁HK, Coxsackievirus B5a, Poliovirus 1 & 2, Adenovirus-2, Rhinovirus, Rotavirus SA-11, Cytomegalovirus, Respiratory Syncytial Virus, and Vaccinia virus.
ColdSpor 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 1:20 diluted solution for 30 days in manual (bucket or tray) systems. 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 10 minute contact time for disinfection against all of the organisms claimed. See COLDSPOR HIV-1 (AIDS VIRUS) INFORMATION included as a package insert.
Remove instruments using aseptic technique, rinse with potable water, and dry. Not to be used in metal trays, or as an overnight holding solution. This solution may be used and reused for up to 30 days in a manual bucket system.
STERILIZATION: All articles to be sterilized must be thoroughly cleaned and rough dried before placing in sterilizing solution prepared by making a 1:5 dilution of the solution (1 part of ColdSpor plus 4 parts tap water), or by pouring entire contents of this container (8.4 oz) into an empty one quart container and filling with tap water. Completely immerse instruments in solution diluted 1:5 for 10 hours at room temperature (20°C/68°F). Remove instruments using aseptic technique, rinse with sterile water and dry. This solution may be used and reused for up to 30 days.
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.
PRODUCTION LOT NUMBER IS STAMPED ON BOTTOM OF CONTAINER.
USE RECOMMENDATIONS: Especially recommended for sterilization or disinfection of medical instruments, dental instruments, sharp instruments, forceps, cages, plastic objects, rubber objects, aluminum objects, thermometers and endoscopes. Medical instruments used in Anesthesiology, Endoscopy, Respiratory Therapy, Surgery, and Urology, and Dental Instruments such as Hemostats, Diamond Bionics, Mirrors,

BEST AVAILABLE CO

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KVMK COPY (DATE) Client: Metra Research Corp. PO 6393
File Name: ColdSpor310 Disk WETX Dress 1.3 Density 2.9