

FM 31 55195-3 10/2

JAN 1 1991

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Colcide, Inc.
909 Pershing Drive
Silver Spring, MD 20910

Attention: Kyle H. Sibinovic
Agent

Gentlemen:

Subject: Colcide 0.25%
EPA Registration No. 55195-3
Your Amendment Dated October 21, 1990

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

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

a. Revise "Additional Precautions and First Aid" to read:

Precautionary Statements
Hazards To Humans and Domestic Animals

b. Change the "First Aid" heading to read:

Statement of Practical Treatment

c. Change "EPA Registration No. 55195-3-46781" to read "EPA Registration No. 55195-3."

d. Revise "See first aid and other precautions on side panel" to read "See side panel for additional precautionary statements."

e. On the right panel, include instructions for the NIV-1 claim. Refer to the enclosed "Example" for proper formatting.

56362;I-WP5-0;DeLaney;G;D;ek;E;M;CO;12/20/90;da;vo;ek;de

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

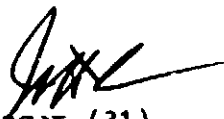
2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). 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

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ACCEPTED
with COMMENTS
to EPA Letter Dated:

JAN 14 1991

Under the
Fungicide,
as amended,
registered under EPA Reg. No.
55195-3

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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 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, exam tables, cages, plastic and other similar hard surfaces.

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

At this concentration, ColdCide-0.25% kills *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Trichophyton mentagrophytes*. *Mycobacterium tuberculosis* is completely inactivated in 15 minutes at room temperature (25°C or higher). Herpes simplex virus 1 & 2 and Influenza A₁ HK are completely inactivated in 30 seconds, and the listed viruses* within 2 minutes at 20°C/68°F or higher: Coxsackievirus B5a, Adenovirus-2, Poliovirus 1 & 2, Rotavirus SA-11, Rhinovirus, Vaccinia virus, Cytomegalovirus and Respiratory Syncytial Virus.

ColdCide-0.25% 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.

Product No.

MX-5320

Active Ingredients:

Glutaraldehyde 0.25%
O-Phenylphenol 0.125%
P-Tertiary Amylphenol 0.0125%
Inert Ingredients: 99.8125%
TOTAL 100.0000%

EXPIRATION DATE: 2 YEARS
AFTER DATE MANUFACTURED

Patented
E.P.A. Reg. No. 55195-3-
E.P.A. Est. No. 46781-CO-01

Glutaraldehyde Synergistic Dual Phenolics
Disinfecting Solution

ColdCide

0.25%

For use as a pump spray or wipe
*Stable, low pH formula

*Bactericidal | *Pseudomonacidal
Virucidal | *Fungicidal
*Tuberculocidal

Keep out of reach of children.
CAUTION: See first aid and other precautions
on side panel.