

7/15/97

194

JUL 15 1997

Colcide, Inc.  
11500 W. Hill Drive  
Rockville, Md 20852

Attn: Kyle Sabinovic, Ph.D

Subject: ColdCide-0.25% Disinfectant Wipes  
EPA Registration No. 55195-4  
Amendment Dated June 24, 1997

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, with respect to the amount of para tertiary amyl phenol on the label, is acceptable, provided that you make the following changes listed below.

- In the use directions, delete the uses "supply", "dressing" and "plastic and other similar hard surfaces."

Submit one (1) copy of revised final printed label before you release the product for shipment bearing the amended labeling. A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell  
Acting Product Manager (33)  
Regulatory Management Branch 1  
Antimicrobial Division (7510W)

Enclosure

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

294

New Light Floral Scent

## ColdCide

### 0.25% DISINFECTING WIPES

A stable, low pH formulated disinfectant and deodorant for use in hospitals, medical offices, dental offices, veterinary facilities, janitorial, commercial and industrial facilities for use on hard surfaces..

Bactericidal  
Virucidal\*  
Pseudomonocidal  
Fungicidal  
Tuberculocidal

Active Ingredients	
Glutaraldehyde	0.27500%
O-Phenylphenol	0.01375%
P-Tertiary Amylphenol	0.00275%
Inert Ingredients**	99.70850%
<b>TOTAL</b>	<b>100.0000%</b>

\*\*Does not include weight of dry wipe.

Contents: 160 Wipes Saturated with Disinfectant

## CAUTION

### KEEP OUT OF REACH OF CHILDREN

See side panel for additional precautionary statements.

Kills Herpes simplex virus types 1 & 2, Influenza A2 (Hong Kong) & HIV-1 (AIDS virus)\* on hard non-porous surfaces.

**PREPARATION OF DISPENSER:** Open top of tub, remove and discard covering seal. From center of wipes roll, pull up a wipe corner, twist into a point and thread through the X hole in the underside of the lid cover. Pull wipe through about one (1) inch. Replace the lid cover on container, assuring a secure fit. Pull out first wipe and snap at a 90° angle. Remaining wipes feed automatically for next use. Always reseal hinged cap after each use to insure moisture retention.

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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

Manufactured by: Dymon, Inc.  
3401 Kansas Ave.  
Kansas City, KS 66106

For: ColCide, Inc.  
11500 W. Hill Dr.  
Rockville, MD 20852

EPA Reg. No. 55195-4  
EPA Est. No. 11694-KS-1

ACCEPTED  
with COMMENTS  
to EPA Reg. No. 55195-4

JUL 15 1997

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
55195-4

394

**DIRECTIONS FOR USE:**

It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling. Thoroughly wet pre-cleaned surface with a wipe and allow to air dry. For use as a general disinfectant wipe on hard, inanimate surfaces such as counter tops, exam tables, cages, toilets, basins, tubs, bed springs, frames, bedside and office furniture, chart racks and equipment, cabinets, door knobs, office machinery, sinks, mirrors, light fixtures and switches, supply, dressing, and trash carts, telephones, waste cans and laundry hampers, wheel chairs, and walkers, urinals, plastic and other similar hard surfaces.

**DISINFECTION:**

ColdCide - 0.25% Disinfecting Wipes kill *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Trichophyton mentagrophytes* in 10 minutes at 20°C/68°F or higher. *Mycobacterium tuberculosis* is completely inactivated in 20 minutes at room temperature (20-25°C or higher). Herpes simplex virus 1 & 2 and Influenza A<sub>2</sub>HK are inactivated in 30 seconds, and the listed viruses\* within 2 minutes at 20°C/68°F or higher. Coxsackie virus B5a, Adenovirus-2, Poliovirus 1&2, Rotavirus SA-11, Rhinovirus, Vaccinia virus, Cytomegalovirus and Respiratory Syncytial Virus.

ColdCide-0.25% Disinfecting Wipes inactivate the HIV-1 (AIDS virus) on hard, non-porous surfaces in 30 seconds at room temperature (20-25°C).

**DEODORIZING:** Wipe hard, non-porous surface thoroughly to eliminate odors from post-colostomy, post-ileostomy dressing and bags, malignant diseases, bathrooms, industrial plant processes, fecal matter, urine, burns, smoke, mildew and mold, decay, stale air, tobacco, sickrooms and musty closets.

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in EPA Letter Dated  
11/15/1997  
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55795-4

**PRECAUTIONARY STATEMENTS:**

Hazards 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. 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 WIPES.**

**STORAGE AND DISPOSAL:**

Store in cool area. Do not reuse wipes. Dispose of used wipe and empty dispenser in trash.

**THE ACTIVITY OF COLDcide 0.25% DISINFECTING WIPES AGAINST THE HIV-1 (AIDS VIRUS):**

ColdCide - 0.25% Disinfecting Wipes completely inactivate the HIV-1 (AIDS virus) on hard, non-porous surfaces when used 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 20 minute contact time for disinfection against all of the organisms claimed on the label. ColdCide 0.25% Disinfecting Wipes kill HIV-1 on pre-cleaned environmental surfaces/objects 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 or eye coverings.

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

**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.

**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.

U.S. Patent #4,469,614 & 4,654,374 / Additional Patent Pending

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