

8/9/2012



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

ITW Dymon
c/o for Colcide, Inc
805 E. Old 56 Highway
Olathe, KS 66061

AUG 9 2012

Attention: Melissa Schnake
Regulatory Specialist

Subject: **Colcide** 0.25% Disinfecting Wipes
EPA Reg. No. 55195-4
Application Dated March 30, 2012

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. The Agency has no objection to the revising of your label to reflect removing tuberculosis (TB) claims from your Master label. A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

A handwritten signature in black ink, appearing to read "M Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

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MASTER LABEL
All word(s), phrases, or symbols in {} and bolded are OPTIONAL

COLDCIDE 0.25% WIPES

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03-30-2012

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*
Pseudomonicidal
Fungicidal

Active Ingredients	
Glutaraldehyde	0.27500%
O-Phenylphenol	0.01375%
P-Tertiary Amylphenol	0.00275%
Inert Ingredients**	99.70850%
TOTAL	100.00000%

**Does not include weight of dry wipe.

Net Contents: XX lbs xx oz (XXX grams)
Contains: XXX xx in X xx in ((xx cm X xx cm))

{Wipe} {s} {Saturated with Disinfectant} {Disinfectant} {Disinfecting} Wipes}

CAUTION

KEEP OUT OF REACH OF CHILDREN

See {side} {back} {rear} {attached} panel {label} for additional precautionary statements.

Kills Herpes simplex virus types 1 & 2, Methicillin-Resistant Staphylococcus Aureus (MRSA) & HIV-1 (AIDS virus)* on hard non-porous surfaces.

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)

{following complete paragraph omitted on single pack container}

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

EPA Reg. No. 55195-4-{XXXXXX}

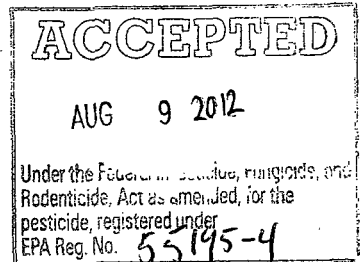
EPA Est. No. 11694-KS-1

{Manufactured} {Sold} {Distributed} {in the U.S.A.} {by} {for}

{ITW Dymon}
{805 E. Old 56 Highway}
{Olathe, KS 66061}

{ColCide, Inc.}
{11500 W. Hill Dr.}
{Rockville, MD 20852}

{PRODUCT/MSDS DOCUMENT # xxxxx}



{Box border optional}

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 rubber gloves when handling. Repeated dermal contact may result in dermal sensitization in some individuals. Avoid contamination of food. Avoid reuse of unwashed, disinfectant-soaked gloves. Avoid prolonged inhalation.

{Box border optional}

FIRST AID:

IF IN EYES: Hold eye open. Rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then, continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

WASH THOROUGHLY AFTER HANDLING WIPES.**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

Store in cool area inaccessible to children.

CONTAINER STORAGE/DISPOSAL: Wipes: Dispose of (wipe) (towel) in trash after use. Do not flush. Canister: Tightly close lid between uses to retain moisture. Nonrefillable container. Do not reuse or refill this (container) (canister). Offer empty (container) (canister) for recycling if available or discard 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 and 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 must be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

{For an MSDS, call XXXXXXXXXXXX or visit www.wwwwwwwww.com and request document XXXXX.}

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

