

55195-4

3/9/2010

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Colcide, Inc.
11500 W. Hill Dr.
Rockville, MD 20852
Sturtevant, WI. 53177-0902

MAR 09 2010

Attention: Melissa Schnake
Regulatory Specialist

Subject: **Colcide** 0.25% Disinfecting Wips
EPA Reg. No. 55195-4
Amendment Letter Dated October 9, 2009

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable. Below are some minor labeling revisions that should be incorporated:

- The directions must be revised to include the language, "Use as many wipes as needed for the surface to remain wet for the entire contact time."
- Directions for Use need to include instructions for cleaning prior to use of the product.
- Add the words "non-porous" to include instructions for cleaning prior to use of the product.
- Disinfection directions do not include one single contact time for disinfection. The applicant needs to include a contact time in the directions for use sections. Claims against different organisms may be made elsewhere but directions for use as disinfectant need to include one clear contact time, i.e. 10 minutes unless against tuberculosis (TB).
- On the front page of the proposed label, please remove the term, "Intermediate Disinfectant". The Agency does not classify disinfectants as "intermediate".
- *delete the* A claim against Mycobacterium tuberculosis was previously accepted with a contact time of 20 minutes. This length of contact time is not practical for end use or a wipe product. The maximum contact time that has been historically allowed for non-immersable uses is 10 minutes. This claim is misleading and represents a false sense of efficacy against TB since the surface would not likely remain wet for 20 minutes. Therefore, your company must submit confirmatory data to prove that the product is efficacious against TB at ~~20~~ 10 minutes or less.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

If the above 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 accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

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", is written over the typed name.

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

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
[REDACTED]

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 # xxxxxx}

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 09 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
"ColdCide 0.25% Wipes"

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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. 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*, *Methicillin-Resistant Staphylococcus aureus (MRSA)*, *Pseudomonas aeruginosa*, *Trichophyton mentagrophytes*, and Human Coronavirus (HCoV) in 10 minutes at 20°C/68°F or higher. ~~*Mycobacterium tuberculosis* is inactivated in 20 minutes at room temperature (20-25°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 virus B5a, Adenovirus-2, Poliovirus 1&2, Rotavirus SA-11, Rhinovirus, Vaccinia virus, Cytomegalovirus and Respiratory Syncytial Virus. Kills Pandemic H1N1 influenza A virus (formerly called swine flu).

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 surfaces thoroughly to eliminate odors due to spillage from {post-colostomy,} {post-ileostomy} {dressing} {s} and {bag change {s}, {and other} spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

ACCEPTED
with COMMENTS
to EPA Letter Dated:

MAR 09 2010

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

65145-4

{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:

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 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 XXXXXXXXXX or visit www.xxxxxxxx.com and request document XXXXX.}

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