

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

55195-4

4/28/2004

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APR 28 2004

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

Attention: Kyle H. Sibinovic, Agent

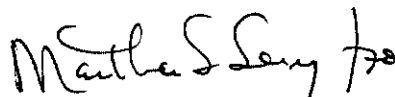
Subject: ColdCide 0.25% Disinfectant Wipes
EPA Registration No. 55195-4
Your Notification Dated March 31, 2004

This will acknowledge receipt of your notification to include an additional pack size for the above product, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

The notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703) 308-6237.

Sincerely



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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2 3 5

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0090, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 55195-4	2. EPA Product Manager Mr. Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ColdCide 0.25% Disinfecting Wipes	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) ColCide, Inc 11500 W. Hill Dr Rockville, MD 20852 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Additional pack size. This notification is consistent with the provisions of PRN 98-10 and EPA regs at 40CFR152.46 and no other changes have been made to labeling or to CSF of this product. I understand that it is a violation of 18 USC Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PRN 98-10 and 40CFR152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container 1	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Single towelette		5. Location of Label Directions <input checked="" type="checkbox"/> On front and back of package	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kyle H Sabinovic, PhD	Title Agent	Telephone No. (Include Area Code) 301-895-1200
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Kyle H Sabinovic, PhD	5. Date 03-31-2004	

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SHALDRA, INC.
4327 REELS MILL RD - FREDERICK, MD 21704-7759
PHONE: (301) 695-1200 FAX: (301) 695-1409
email: shaldra@starpower.net

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Crystal Mall 2, Room 266A
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: ColdCide 0.25% Disinfecting Wipes
EPA Reg. No. 55195-4
Re: Notification of additional package size -single
towel package per PR Notice 98-10
OPP ID NO.
03-31-2004

To Whom It May Concern:

As requested by Mr. Swindell, Product Manager (33), Antimicrobial Programs Division (7510W), enclosed please find the following notification:

1. Transmittal letter
2. Application for Pesticide Notification (OPP ID #
3. Five (5) copies of the label for the single package unit.
4. Copy of the currently approved master label for this product.

Note all print sizes on the new single pack are 6 pt or larger as required.

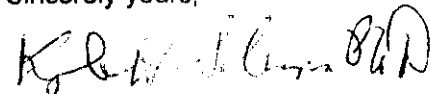
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

My client is hopeful that this submission will be handled as expeditiously as possible.

Should you have any questions, please feel free to contact me at the above address, by phone or email.

Thanking you for your consideration of this notification, I am

Sincerely yours,



Kyle H. Sabinovic, Ph.D.
Agent for ColCide, Inc.

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THE EYESP
HERE WILL
THE FINISH
DETERMINE
DYMOM. PLEASE
PLACE THE
SUBMITTED

DIRECTIONS FOR USE:

It is a violation of 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.

DISINFECTION: ColdCide 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/68-77°F or higher). Herpes simplex virus 1 & 2 and Influenza A₁H1N1 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, Rabies virus, Vaccinia virus, Cytomegalovirus and Respiratory Syncytial Virus. ColdCide Wipes inactivate the HIV-1 (AIDS virus) on hard, non-porous surfaces in 30 seconds at room temperature (20-25°C/68-77°F).

DEODORIZING: Wipe hard, non-porous surface thoroughly to eliminate odors from post-colostomy, post-ileostomy, dressings and bag changes and other spills such as urine or fecal matter, smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

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.

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 and safety glasses 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.

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

THE ACTIVITY OF ColdCide Wipes AGAINST THE HIV-1 (AIDS VIRUS): ColdCide 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/68-77°F). 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 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 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 and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

030723

8 pt (Storage and Disp

9 pt

9 pt

10 pt

6 pt

6 pt

12 pt

8 pt

Contains 1 - 6" x 8" Wipe

See back panel for additional precautionary statements.

WASH THOROUGHLY AFTER HANDLING WIPES. Hold eyes 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.

CAUTION

KEEP OUT OF REACH OF CHILDREN