

34810-35

2/15/2012

116

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

FEB 15 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mary Anne Auer
Wexford Labs, Inc.
325 Leffingwell Avenue
Kirkwood, MO 63122

Subject:
EPA Registration Number: 34810-35
Application Date: January 16, 2012
Receipt Date: January 17, 2012

Dear Ms. Auer:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide (FIFRA), as amended, is acceptable.

Proposed Amendment

- Updating Label: Adding moving NSF graphics
Adding Spanish Signal Word

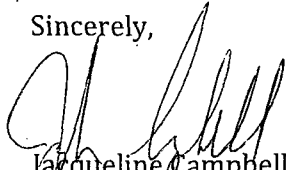
General Comments

A stamped label is enclosed for your records.

Submit 3 copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If you have further questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 308-6440 or by email at grigsby.stacey@epa.gov. When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,



Jacqueline Campbell
Product Manager 34

Regional Management Branch II
Antimicrobials Division (7510P)

SYMBOL	Enclosure: stamped label						
SURNAME							
DATE							



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 34810-35	2. EPA Product Manager Jacqueline McFarlane	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CleanCide	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Wexford Labs, Inc. 325 Leffingwell Avenue Kirkwood, MO 63122 <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 checked="" type="checkbox"/> Final printed labels in response to Agency letter dated <u>03/12/2010</u>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

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

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.

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
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt. 995 grams	No. per container 12	Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 10" H x 3.25" W		5. Location of Label Directions <input type="checkbox"/> On the bottle	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other <u>silk-screened on the bottle</u>		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Mary Anne Auer	Title CEO	Telephone No. (Include Area Code) 314-966-4334
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 CEO	
4. Typed Name Mary Anne Auer	5. Date 01/16/2012	

Wexford Labs

Disinfectant Solutions

January 16, 2012

Ms. Jacqueline McFarlane
(Acting) Product Manager (34)
Regulatory Management Branch II
United States Environmental Protection Agency
Antimicrobial Division (7510P)
2777 Crystal Drive
Potomac Yard 1
Arlington, VA 22202

Re: 34810-35 CleanCide Label revisions in response to Agency Letter dated March 12, 2010

Dear Ms. McFarlane:

I have enclosed the following:

- Form 8570-1 Notification for CleanCide (EPA # 34810-35)
- Copy of the Agency Letter dated: March 12, 2010
- Copy of the CleanCide (EPA # 34810-35) updated master label
- 3 Copies of the CleanCide (EPA # 34810-35) final printed label

I thought I had already submitted these, but I can find no record of it. I believe it was set aside because of all the ATP activity.

I appreciate your assistance with this process.

Sincerely,
WEXFORD LABS, INC.

Mary Anne Auer
CEO

Enclosures

```

c c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c
c c c c c c c

```

4/6

**CLEAN-CIDE
READY TO USE
GERMICIDAL DETERGENT
CLEANS • DISINFECTS • DEODORIZES
GERMICIDAL, PSEUDOMONACIDAL, TUBERCULOCIDAL,
FUNGICIDAL and VIRUCIDAL***

ACTIVE INGREDIENT:	
Citric Acid	0.60%
OTHER INGREDIENTS:	<u>99.40%</u>
TOTAL	100.00%

NOTIFICATION
Date Reviewed: 2/15/2012
Reviewed By: [Signature]

EPA Reg. No. 34810-35 EPA Est. No. 34810-MO-1

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

In the presence of 5% blood serum and a contact time of 5 minutes, is effective against:

GERMICIDAL: Pseudomonas aeruginosa [ATCC 15442], Staphylococcus aureus [ATCC 6538], Salmonella (choleraesuis) enterica [ATCC 10708], Listeria monocytogenes [ATCC 19117], Escherichia Coli O157:H7 [ATCC 43888], Staphylococcus aureus - MRSA [ATCC 33592], Staphylococcus epidermis - MRSE [ATCC 51625], Enterococcus faecalis Vancomycin Resistant (VRE) [ATCC 51575] **VIRUCIDAL*:** Respiratory Syncytial Virus, Rotavirus, Human Immunodeficiency Virus Type 1 (Strain HTLV-III_B), Herpes Simplex Type 1 Virus, Herpes Simplex Type 2 Virus (Strain G), Vaccinia Virus, Influenza A Virus (Strain Hong Kong), Pandemic 2009 H1N1 Influenza A Virus (formerly called swine flu), Adenovirus Type 2, Feline Calicivirus (surrogate for Norovirus) **FUNGICIDAL:** Trichophyton mentagrophytes [ATCC 9533]

In the presence of 5% blood serum and a contact time of 10 minutes, is effective against:

GERMICIDAL: Acinetobacter baumannii [19606] **VIRUCIDAL:** Canine Parvovirus (CPV), Hepatitis B Virus (HBV), Poliovirus Type 1

TUBERCULOCIDAL: Effective against Mycobacterium bovis [ATCC 35743] in 5 minutes at 20°C / 68°F on previously cleaned hard non-porous inanimate surfaces.

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing. Call a Poison Control Center or doctor for further treatment advice.

Wexford Labs, Inc. 325 Leffingwell Avenue Kirkwood, Missouri 63122
Net Contents: One Quart

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Product is ready to use. **DO NOT DILUTE.**

TO CLEAN: Apply Clean-Cide undiluted to hard, non-porous surfaces by wiping with a cloth or towel until clean.

TO DISINFECT AND DEODORIZE: Apply the Clean-Cide product undiluted to hard, non-porous surfaces with a cloth, mop or brush, or by immersing equipment to be disinfected. Wet all surfaces thoroughly. The surface must remain wet with Clean-Cide for at least 10 minutes. Wipe or let air dry. Preclean areas with gross filth and heavy soil prior to disinfection.

FUNGICIDAL DIRECTION: This product is effective against Trichophyton mentagrophytes (athletes foot fungus and a cause of ringworm) on inanimate surfaces in locker rooms, dressing rooms, exercise facilities, and shower and bath areas. Follow disinfection directions

[AREAS OF USE:]

- | | |
|---|----------------------------|
| [Hospitals] | [Nursing homes] |
| [Health Care Facilities] | [Bathrooms] |
| [Medical Offices] | [Institutions] |
| [Dental offices] | [Institutional facilities] |
| [Day care centers] | [Kennels] |
| [Nurseries] | [Grooming Facilities] |
| [Schools] | [Veterinary Clinics] |
| [Laboratories or other small animal facilities] | |

[TYPES OF SURFACES:]

[On washable hard, nonporous surfaces of:]

- | | |
|--------------------|--------------------------------|
| [Floors] | [Stainless Steel] |
| [Walls] | [Chrome] |
| [Fixtures] | [Glass] |
| [Furniture] | [Vinyl] |
| [Metal] | [CuVerro antimicrobial copper] |
| [Glazed porcelain] | [Glazed ceramic tile] |
| [Baked Enamel] | [Plastic] |

DECONTAMINATION OF CRITICAL OR SEMI-CRITICAL DEVICES PRIOR TO TERMINAL STERILIZATION/HIGH LEVEL DISINFECTION: 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.

***CLEAN-CIDE KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in all settings in which there is an expected likelihood of soiling of hard, non-porous 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 DECONTAMINATING SURFACES/OBJECTS SOILED WITH BLOOD AND BODY FLUIDS WHICH MAY CONTAIN HIV-1 (AIDS virus).

PERSONAL PROTECTION: When handling objects soiled with blood or body fluids use disposable latex gloves, gowns, mask or eye coverings.

6/6

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

CONTACT TIME: Do Not Dilute. Leave precleaned surfaces wet for five minutes using mop, cloth or sponge to mitigate HIV-1 virus. Use a 10 minute contact time to kill all bacteria, viruses* and fungi listed on the label.

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other fluids should be autoclaved and disposed of according to Federal, State and Local regulations for infectious waste disposal.

[Veterinary Practice / Animal Care / Animal Laboratory / Zoos / Pet Shop / Kennels Disinfection

Directions: For cleaning and disinfecting hard nonporous surfaces: equipment used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with Clean-Cide for a period of 10 minutes. Wipe or allow to air dry. Thoroughly scrub all treated surfaces that come into contact with food, including equipment used for feeding or watering, with soap or detergent and rinse with potable water before reuse. Do not house animals or employ equipment until treatment has been absorbed, set or dried.]

STORAGE AND DISPOSAL:

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

Pesticide Storage: Store in original container in areas inaccessible to children.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. If not, puncture and dispose of in a sanitary landfill.

Made in the USA

MSDS #: 2130-02

Reorder #: 2130-02

Revised: 03/22/10

