

34810-36

8/7/2014

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

AUG 7 2014

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

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

Subject: **CleanCide Wipes**  
EPA Registration No.: 34810-36  
Application Date: July 8, 2014  
Receipt Date: July 9, 2014

Dear Dr. Auer:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c) 9.

**Proposed Notification:**

- Adding optional marketing language
- Dispenser directions
- Remove "do not dilute"

**General Comment:**

Based on a review of the material submitted, your notification to update as referenced above is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at [hardy.jacqueline@epa.gov](mailto:hardy.jacqueline@epa.gov) or Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at [grigsby.stacey@epa.gov](mailto:grigsby.stacey@epa.gov) during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacqueline Hardy".

Jacqueline Hardy  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)



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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 34810-36	2. EPA Product Manager Jacqueline Campbell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CleanCide Wipes	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 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.)

Adding optional marketing language. Adding dispenser directions, which were accidentally deleted from master label. Remove "do not dilute" which was accidentally carried copied over from CleanCide Ready to Use liquid label.

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
* Certification must be submitted	If "Yes" Unit Packaging wgt. 1200 and 1075	No. per container 60 and 160	If "Yes" Package wgt	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 6.75" H x 5" W		5. Location of Label Directions <input type="checkbox"/>		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph Paper glued Stenciled			<input checked="" type="checkbox"/> Other Self-adhering sticker		

### 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) 314-966-4134
<b>Certification</b> 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  <b>(Stamped)</b>
2. Signature 	3. Title CEO	
4. Typed Name Mary Anne Auer	5. Date 07/08/2014	

# Wexford Labs

Disinfectant Solutions

July 8, 2014

Ms. Jacqueline Campbell  
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: 34810-36 CleanCide Wipes: Additional marketing language, revise directions for use to include dispenser directions.

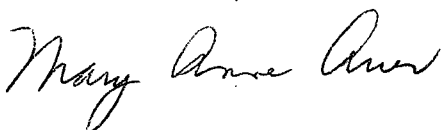
Dear Ms. Campbell:

I have enclosed the following:

- Form 8570-1 Notification for CleanCide Wipes (EPA # 34810-36)
- 3 Copies of the CleanCide Wipes (EPA # 34810-36) updated master label with changes highlighted:
  - Under Directions for use, Dispenser Directions were added; these were inadvertently dropped on our last revisions. "DO NOT DILUTE" was deleted. This was carried over in error from our CleanCide liquid product.
  - Added optional language: "Includes biodegradable detergents", "disinfectant wipe", "disinfecting wipe"

I appreciate your assistance with this process.

Sincerely,  
WEXFORD LABS, INC.



Mary Anne Auer  
CEO

Enclosures

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**CLEANCIDE WIPES  
[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%

EPA Reg. No. 34810-36 EPA Est. No. XXXXXXX

**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 enterica (*formerly Salmonella Choleraesuis*) [ATCC 10708], [Klebsiella pneumoniae [ATCC 4352]], [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<sub>B</sub>)],[ 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 [ATCC 19606] **VIRUCIDAL:** Canine Parvovirus (CPV), Hepatitis B Virus (HBV), Poliovirus Type 1]

**[TUBERCULOCIDAL:** Effective against Mycobacterium bovis (BCG) [Organon Teknika Corp.]] 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.

NET CONTENTS: X lbs, X oz.

X Pre-moistened Towelettes (X)" x (X)"  
(e.g. 100 Pre- moistened Towelettes 7"x 8")

**Wexford Labs, Inc. 325 Leffingwell Avenue Kirkwood, Missouri 63122**

**Marketing Claims:**

[Bleach Free]  
 [(Antibacterial) Kitchen Cleaner]  
 [(Antibacterial) bathroom cleaner]  
 [(Antibacterial) household cleaner]  
 [Disinfects while you clean]  
 [Clean and disinfect in one step]  
 [Kills 99% (99.9%) of (household) germs]  
 [Quick and easy cleaning]  
 [Effectively controls odor]  
 [Eliminates odor-causing bacteria]  
 [Multi-Purpose]  
 [Multi-Surface]  
 [Dye free]  
 [Disinfecting Wipe]  
 [Disinfectant Wipe]

**Fragrance Descriptors:**

[Fragrance free]	[Dye and Fragrance free]
[Citrus]	[Clean and Fresh]
[Floral]	[Ocean Breeze]
[Orange]	[Peach]
[Tropical]	[Wintermint]
[crystal Mint]	[Arctic breeze]
[Cleanmint]	[Glacier Mint]
[Wintergreen]	[Clean Mint]
[Cool Mint]	[Winter Fresh]
[Mint]	[Pear]
[Strawberry]	[Cherry]
[Pine]	[Citrus Splash]
[Fresh Meadows]	[Floral Woods]
[Fresh Citrus]	[Lemon Verbena]
[Fresh Squeezed]	[Citrus Fresh]
[Orange]	[Orange Fresh]
[Citrus Burst]	

**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.** Preclean areas with gross filth and heavy soil prior to disinfection.

**DISPENSER DIRECTIONS:** To start feed, remove large cover. Pull up the towelette corner from the center of the towelette roll, twist it into a point and thread it through the hole in the container cover. Pull through about one inch. Replace cover. Pull out first towelette and snap off at a 90° angle. Remaining towelettes feed automatically ready for their next use. When through using, keep small center cap closed to prevent moisture loss.

**TO CLEAN/DEODORIZE:** Unfold premoistened cloth and wipe area to be cleaned for 30 seconds or until clean.

(Spot check to test for compatibility)

**TO DISINFECT:** Unfold premoistened cloth and wipe hard non-porous area or item to be disinfected. Wet all surfaces thoroughly. (The surface must remain wet with CleanCide for at least) (Leave for ) (5) (10) minutes. *Contact time in accordance with organisms listed on the distributed product label.* Wipe or let air dry. No rinsing or wiping is required, except on direct food contact surfaces which require a potable water rinse after treatment. Toys: Use only on hard non-porous surfaces and rinse after treatment. **FUNGICIDAL DIRECTIONS:** This product is effective against Trichophyton mentagrophytes (athlete's 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.

**Rinse toys and food contact surfaces with potable water.**

**USAGE CLAIMS**

(Suitable) (Intended) for use on (in)

[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] |                            |
| [Kitchens]                                      |                            |

[TYPES OF SURFACES/USE SITES:] (Graphic –depicting surface)

- [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]                      |
| [Children's toys]  | [Garbage Cans]                 |
| [Toilet Seats]     | [Pet Habitats]                 |
| [Countertops]      | [Appliances]                   |
| [Changing tables]  | [High chairs]                  |
| [Kitchen surfaces] |                                |

Where medical devices are listed as applicable sites, the following will be included as required by PR 94-4

**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.

*The following special instructions should be included on the label if the product is used as a hospital-grade disinfectant rather than retail/household.*

**\*CLEANCIDE 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 and eye coverings.

**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 CleanCide 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 leave containers open during storage. No special handling is required. **Towelette:** Do not reuse towelette. Dispose of used towelette in trash. **Dispenser:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available.

[Made in (insert country)]  
[Barcode]

MSDS #: xxxxx

Reorder #: xxxx-xx

Revised: 07/16/2012

[The following graphics are optional. They will be affixed to the label/canister so that it does not interfere with any label text.]

