

34810-36

12/8/2012

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DEC 8 2012

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

Subject: CleanCide Wipes
EPA Registration No.: 34810-36
Amendment Date: July 17, 2012
EPA Receipt Date: July 18, 2012

Dear Ms. Auer

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable.

Proposed Amendment

- Adding use sites and optional marketing claims
- Adding claims against *K. pneumoniae* and *M. bovis*

Data Evaluation

Data Requirement	Means of Support	Status
Impregnated Towelletes for Hard Surface Disinfection – <i>K. pneumoniae</i>	Submitted study, MRID 48887702	Acceptable, RTU @ 5 min
Impregnated Towelletes for Tuberculocidal Effectiveness	Submitted study, MRID 48887703	Acceptable, RTU @ 5 min

General Comments

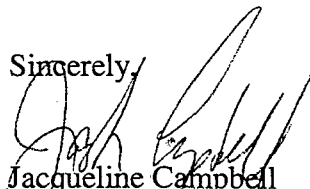
A stamped copy of the accepted label is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) 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.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6416 or by e-mail at Campbell-mcfarlane.jacqueline@epa.gov or Lorena Rivas at (703) 305-5027 or by email at rivas.lorena@epa.gov.

Sincerely,



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

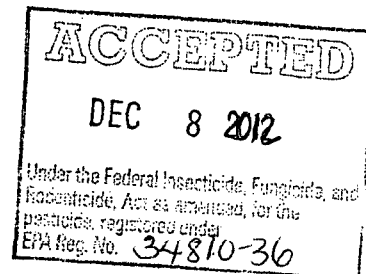
Enclosure: Stamped Label

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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: 99.40%
TOTAL 100.00%

EPA Reg. No. 34810-35 EPA Est. No. XXXXXX



**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_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 [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]

Fragrance Descriptors:

[Fragrance free]	[Dye and Fragrance free]
[Citrus]	[Clean and Fresh]
[Floral]	[Ocean Breeze]
[Orange]	[Peach]
[Tropical]	[Wintermint]
[crystal Mint]	[Arctic breeze]
[Clean mint]	[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.

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] | |

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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 pre-clean 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 pre-cleaned 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.]

