



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 6, 2017

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

Subject: PRIA Label Amendment – Add five new organisms
Product Name: Cleancide
EPA Registration Number: 34810-35
Application Date: June 29, 2017
Decision Number: 531522

Dear Ms. Auer:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Page 2 of 2
EPA Reg. No. 34810-35
Decision No. 531522

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Tom Luminello by phone at (703) 308-8075, or via email at luminello.tom@epa.gov.

Sincerely,



Jacqueline Hardy, PM 34
Regulatory Management Branch 2
Antimicrobials Division (7510P)

Enclosure Stamped Label

**[CLEANCIDE®]
[READY TO USE]
[GERMICIDAL DETERGENT]
[CLEANS] • [DISINFECTS] • [DEODORIZES]
[GERMICIDAL], [PSEUDOMONACIDAL], [TUBERCULOCIDAL],
[FUNGICIDAL] and [VIRUCIDAL*] [SANITIZER]**

ACTIVE INGREDIENT:

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

**KEEP OUT OF REACH OF CHILDREN
[CAUTION]**

**[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.]

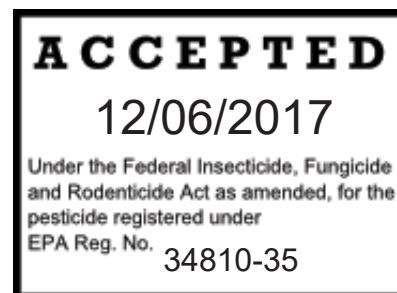
Net contents: _____

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

Efficacy Claims

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

- [GERMICIDAL:]** [Bactericidal] [Bactericidal Activity]
- [Carbapenem-resistant *Klebsiella pneumoniae* ATCC BAA-1705]
- [*Enterococcus faecalis* Vancomycin Resistant [VRE] [ATCC 51575]]
- [*Escherichia coli* O157:H7 [ATCC 43888]]
- [*Listeria monocytogenes* [ATCC 19117]]
- [*Pseudomonas aeruginosa* [ATCC 15442]]
- [*Salmonella enterica* [formerly *Salmonella Choleraesuis*][ATCC 10708]
- [*Staphylococcus aureus* [ATCC 6538]]
- [*Staphylococcus aureus* - MRSA [ATCC 33592]]
- [*Staphylococcus epidermis* - MRSE [ATCC 51625]]



[VIRUCIDAL*:]

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

[Adenovirus Type 2]

[Feline Calicivirus [surrogate for Norovirus]]

[Herpes Simplex Virus Type 1]

[Herpes Simplex Virus Type 2 [Strain G]]

[Human Immunodeficiency Virus Type 1 [Strain HTLV-III_B] (HIV-1) (AIDS Virus)]

[Influenza A Virus [Strain Hong Kong]]

[Pandemic 2009 H1N1 Influenza A Virus [formerly called swine flu]]

[Respiratory Syncytial Virus]

[Rhinovirus [Type 14, Strain 1059]]

[Rotavirus]

[Vaccinia Virus]

[In the presence of 5% blood serum and a] contact time of 3 minutes, is effective against:

[Hepatitis B (HBV), [Duck Hepatitis B (DHBV) as surrogate]]

[Hepatitis C (HBV), [Bovine Viral Diarrhea Virus (BVDV) as surrogate]]

[FUNGICIDAL:]

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

[Candida albicans]

[Trichophyton interdigitale [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], 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.]

[SANITIZER: Staphylococcus aureus [ATCC 6538] and Klebsiella pneumonia [ATCC 4352] in 1 minute [60 seconds].]

OPTIONAL 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
- Suitable for cleaning and deodorizing HVAC air ducts and vents
- Quick and easy cleaning
- Botanical
- Botanical Cleaning
- Naturally derived active ingredient
- Effectively controls odor
- Eliminates odor-causing bacteria

- Multi-Purpose
- Multi-Purpose Cleaner
- Multi-Surface
- Dye free
- Broad Spectrum Hospital Disinfectant
- Carpet Cleaner and Deodorizer
- Bathroom Cleaner
- Non-Irritating
- Non-corrosive
- We're here to help when life happens.
- Change the way you clean with a product that's been designed for your home and the little hands that make them messy
- Change the way you clean with a product that's simple to use and can help clean up life's everyday messes
- Everyday Cleaner
- Inspired by nature

For BoulderClean

[Our name and mission are inspired by the natural beauty of the place we call home: Boulder, Colorado. Surrounded by a landscape rich in breathtaking natural wonders and clean mountain air, we are compelled to provide products inspired by nature to disinfect and clean your home]

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



(Boulder's logo)

<<ALLERGENS>>

- Wipe(s) away dirt [and] [germs][and][allergens†]
- Allergens[†] This product removes the following allergens: [cat dander], [cockroach debris/matter/particles], [dog dander], [dust mite debris/matter/particles], [pet dander], [pollen particles] [from timothy grass], [grass].

Fragrance Descriptors:

[Apple Blossoms]	[Lemon Ginger Reed]
[Apple]	[Lemon Verbena]
[Arctic breeze]	[Lemon Ylang Flower]
[Bramley Apple Blossom]	[Lemon Ylang]
[Cherry]	[Lime Blossom]
[Citrus Burst]	[Mandarin Green Tea]
[Citrus Fresh]	[Mint]
[Citrus Splash]	[Mountain Green]
[Citrus]	[Ocean Breeze]
[Clean and Fresh]	[Orange Fresh]
[Clean Mint]	[Orange Mango Lily]
[Clean Sparkle]	[Orange Mango]
[Cleanmint]	[Orange Zest]
[Cool Mint]	[Orange]
[Cotton Breeze]	[Outdoor Fresh]
[Cotton Lily]	[Pacific Rose Apple]
[Crystal Clean]	[Peach]
[Crystal Mint]	[Pear]
[Cucumber Sage]	[Pine]
[Dye and Fragrance free]	[Pink Grapefruit]
[Floral Woods]	[Ruby Red Grapefruit]
[Floral]	[Scent Free]
[Fragrance free]	[Strawberry]
[Fresh Citrus]	[Sweet Pea Bloom]
[Fresh Meadows]	[Sweet Pea]
[Fresh Squeezed]	[Tropical]
[Glacier Mint]	[Unscented]
[Green Tea Citrus]	[Waterfall Mist]
[Honey Spiced Fig]	[White Diamonds]
[Indian Mango Orange]	[Wild Lemon Ylang]
[Island Springs]	[Wild Lime Verbena]
[Japanese Cherry Blossom]	[Winter Fresh]
[Lavender Vanilla [Orchid]]	[Wintergreen]
[Lemon Breeze]	[Wintermint]
[Lemon Ginger]	

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] visible soil prior to disinfection.

[TO DEODORIZE: Apply to surfaces as needed.]

TO CLEAN: [Apply [this product] undiluted to hard, non-porous surfaces by spraying, wiping with a cloth or towel until clean.] [Spot check to test for compatibility]

OR

[Cleaning Instructions: [spray] [apply to] surface and wipe clean]

[TO SANITIZE: Wet [the] [all] surface[s]. Let stand for 60 seconds [one minute]. Wipe or let air dry. No rinsing or wiping is required.] **TO DISINFECT:** [Apply the [this product] product undiluted to hard, non-porous surfaces with a sprayer, cloth, mop or brush, or by immersing equipment [item] to be disinfected.] Wet all surfaces thoroughly. The surface must remain visibly wet [with this product] [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. **FUNGICIDAL DIRECTION:** 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 with potable water.]

[Toys: Use only on hard non-porous surfaces]

USAGE CLAIMS

[Suitable] [Intended] for use on [in]

[AREAS OF USE:]

for use on hard, non-porous surfaces:

[Athletic Facilities]	[Gyms]
[Classrooms]	[Locker rooms]
[Hospitals]	[Nursing homes]
[Health Care Facilities]	[Bathrooms]
[Medical Offices]	[Institutions]
Dialysis Units	[Kitchens]
[Dental offices]	[Institutional facilities]
[Day care centers]	[Kennels]
[Nurseries]	[Grooming Facilities]
[Residential],	[Prisons]
[Schools]	[Veterinary Clinics]
[Laboratories or other small animal facilities]	
[Restoration and remediation sites [Fire, water, sewage, trauma scene and remediation]]	

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

for use on hard, non-porous surfaces:

[Ambulance patient care surfaces]	[Medical equipment surfaces/devices]
[Anesthesia equipment surfaces]	[Metal]
[Appliances]	[Microscopes]
[Baby/infant care surfaces]	[MRI equipment surfaces]
[Backboards]	[Neonatal/nursery surfaces]
[Baked Enamel]	[Nonporous athletic mats]
[Bathing units]	[Obstetrical equipment surfaces]
[Bathrooms]	[Operating room lights/tables]
[Bed railings]	[Ophthalmic equipment surfaces/devices]
[Beds]	[Optical wear [excluding contact lenses]]
[Blood pressure devices]	[Oxygen hoods]
[Cabinets]	[Patient bed surfaces]
[Chairs]	[Patient stretchers]

[Changing tables]	[Patient transport surfaces]
[Children's toys]	[Pet Habitats]
[Chrome]	[Physical therapy equipment]
[Computer surfaces]	[Plastic]
[Computers]	[Play mats]
[Counters]	[Play-care equipment]
[Countertops]	[Porcelain]
[CPR manikins]	[Radiology equipment surfaces]
[CT equipment/surfaces]	[Refrigerators [exterior surface]]
[Curing lights]	[Respirators]
[CuVerro™ antimicrobial copper]	[Respiratory care equipment surfaces]
[Dental equipment surfaces/devices]	[Sealed granite]
[Doorknobs]	[Shower floors/walls]
[Exam tables]	[Sinks]
[Exercise equipment]	[Skin care equipment/surfaces]
[Fixtures]	[Soaking containers]
[Floors]	[Stainless Steel]
[Furniture]	[Stalls]
[Garbage cans]	[Surgical equipment surfaces]
[Glass]	[Surgical microscopes]
[Glazed ceramic tile]	[Tables]
[Glazed porcelain]	[Telephones]
[Hand railings]	[Toilet Seats]
[Highchairs]	[Toilets [rims, seats and exterior surfaces]]
[HVAC air ducts and vents]	[Toys]
[Immobilization devices]	[Training tables]
[Infant care equipment]	[Transportation equipment surfaces]
[Isolettes]	[Trays]
[Keyboards]	[Vinyl]
[Kitchen surfaces]	[Walls]
[Laboratory equipment/surfaces]	[Work stations]
[Light lens covers]	[Wrestling mats]
[Lights]	[X-ray equipment/surfaces]
[Lumens]	

[TO CLEAN, DEODORIZE AND REMOVE DEBRIS FROM CARPETS AND FABRICS]

[To Spot Clean: Blot or scrub area to be treated with [*Brand name*]
Disinfectant Solution to remove soiling. Wipe dry with clean cloth or towel.

To Deep Clean Carpets, Upholstery and Fabrics: Vacuum to remove loose dirt and soiling. Thoroughly moisten with product using coarse tip pressure sprayer and rake or brush into nap. Clean treated areas using clean water extraction method, such as portable or truck-mounted carpet cleaning machine or upholstery cleaning machine. Allow to dry thoroughly prior to using. Always spot test in inconspicuous area prior to application for compatibility.

Deodorizing and Cleaning of Carpet/Fabrics

To Deodorize and Clean Carpets, Fabrics, and other Materials: [*Brand name*] can be used on most fabrics that can be cleaned with water-based cleaners. Not for use on wool, silk, or suede. Always test for color fastness and material compatibility in an inconspicuous area prior to use. Apply by sprayer, to ensure even coverage and allow for 10 minute contact time. Do not rinse, use hot water extraction wand to remove product from treated surfaces and then dry stroke carpet to remove excess moisture. Carpet can be air dried or fans may be used if carpet needs to dry more quickly.]

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 must be included on the label if the product is used as a hospital-grade disinfectant rather than retail/household.

***[THIS PRODUCT] 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 virus].

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. Precleaned surfaces must remain visibly wet for five minutes using mop, cloth or sponge to mitigate HIV-1 virus. Use a [5] [10] minute contact time to kill all bacteria, viruses* and fungi listed on the label. **Contact time in accordance with organisms listed on the distributed product 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 [this product] 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: Store airtight at room temperature. Nonrefillable container. Do not reuse or refill this empty container. Offer empty container for recycling. If recycling is not available, discard in trash.

EPA Reg. No. 34810-35

EPA Est. No. *[insert Est. No. here]*

For ingredient information, go to www.wexfordlabs.com/DfE/wipes.html

or

A list of this product's ingredients is available at www.IngredientsInside.com

-or- A list of [this product's] [product name] ingredients is available at [insert company website].

NET CONTENTS: [insert container size here]

[Made in [insert country]]

[Barcode]

SDS #: 2130-02

Reorder #: [insert reorder number here]

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



www.epa.gov/pesticides/regulating/labels/design-dfe-pilot.html

Revised: 12/04/2017