



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 20, 2016

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

Subject: Notification per PRN 98-10 –Adding optional marketing language, simplification of storage and disposal instructions optional direction for use language and adding recycle and brand logo

Product Name: CLEANCLIDE
EPA Registration Number: 34810-35
Application Date: June 20, 2016
Decision Number: 518684

Dear Ms. Auer:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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.

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If you have any questions, please contact Stacey Grigsby by phone at 703.305.6440, or via email at grigsby.stacey@epa.gov .

Sincerely,

A handwritten signature in cursive script that reads "Stacey Grigsby".

Stacey Grigsby
Risk Manager
Regulatory Management Branch II
Antimicrobials Division (7510P)

**[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%

EPA Reg. No. 34810-35

NOTIFICATION

34810-35

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

07/20/2016

**[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:]

[Pseudomonas aeruginosa [ATCC 15442]
[Staphylococcus aureus [ATCC 6538],
[Salmonella enterica [formerly Salmonella Choleraesuis][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]

Bold, italicized text is information for the reader and is not part of the label. [Bracketed information is optional text.] **Highlighted text is new.** Strike-through (text) means removed.

[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.]

[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
- 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.

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- Change the way you clean with a product that's been designed for your home and the little hands that make them messy
- 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]
[Apple]
[Arctic breeze]
[Bramley Apple Blossom]
[Cherry]
[Citrus Burst]
[Citrus Fresh]
[Citrus Splash]
[Citrus]
[Clean and Fresh]
[Clean Mint]
[Clean Sparkle]
[Cleanmint]
[Cool Mint]
[Cotton Breeze]
[Crystal Clean]
[Crystal Mint]
[Cucumber Sage]
[Dye and Fragrance free]
[Floral Woods]
[Floral]
[Fragrance free]
[Fresh Citrus]
[Fresh Meadows]
[Fresh Squeezed]
[Glacier Mint]
[Green Tea Citrus]
[Honey Spiced Fig]
[Indian Mango Orange]
[Island Springs]
[Japanese Cherry Blossom]
[Lavender Vanilla [Orchid]]
[Lemon Ginger]
[Lemon Ginger Reed]
[Lemon Ginger Root]
[Lemon Verbena]
[Lemon Ylang Flower]
[Lemon Ylang]
[Mandarin Green Tea]
[Mint]
[Mountain Green]
[Ocean Breeze]
[Orange Fresh]
[Orange Mango Lily]
[Orange Mango]
[Orange Zest]
[Orange]
[Outdoor Fresh]
[Pacific Rose Apple]
[Peach]
[Pear]
[Pine]
[Pink Grapefruit]
[Ruby Red Grapefruit]
[Scent Free]
[Strawberry]
[Sweet Pea Bloom]
[Sweet Pea]
[Tropical]
[Unscented]
[Waterfall Mist]
[White Diamonds]
[Wild Lemon Ylang]
[Wild Lime Verbena]
[Winter Fresh]
[Wintergreen]
[Wintermint]

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 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 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:

[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, decontamination and remediation sites [Fire, water, sewage, trauma scene decontamination and remediation]]	

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

[Ambulance patient care surfaces]	[Lumens]
[Anesthesia equipment surfaces]	[Patient stretchers]
[Appliances]	[Medical equipment surfaces/devices]
[Baby/infant care surfaces]	[Metal]
[Backboards]	[Microscopes]
[Baked Enamel]	[MRI equipment surfaces]
[Bathing units]	[Neonatal/nursery surfaces]
[Bathrooms]	[Nonporous athletic mats]

Bold, italicized text is information for the reader and is not part of the label. [Bracketed information is optional text.] **Highlighted text is new.** Strike-through (text) means removed.

[Bed railings]	[Obstetrical equipment surfaces]
[Beds]	[Operating room lights/tables]
[Blood pressure devices]	[Ophthalmic equipment surfaces/devices]
[Cabinets]	[Optical wear [excluding contact lenses]]
[Chairs]	[Oxygen hoods]
[Changing tables]	[Patient bed surfaces]
[Children's toys]	[Patient transport surfaces]
[Chrome]	[Pet Habitats]
[Computer surfaces]	[Physical therapy equipment]
[Computers]	[Plastic]
[Counters]	[Play mats]
[Countertops]	[Play-care equipment]
[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]]
[Immobilization devices]	[Toys]
[Infant care equipment]	[Training tables]
[Isolettes]	[Transportation equipment surfaces]
[Keyboards]	[Trays]
[Kitchen surfaces]	[Vinyl]
[Laboratory equipment/surfaces]	[Walls]
[Light lens covers]	[Work stations]
[Lights]	[Wrestling mats]
	[X-ray equipment/surfaces]

[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 should 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].

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 [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

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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: 06/20/2016