

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 02, 2018

Cat Kickham Project Manager Wexford Labs, Inc. 325 Leffingwell Avenue Kirkwood, MO 63122

Subject: Label Notification per PRN 98-10 –Adding optional marketing

Language and claims, plus; logos to the Master label

Product Name: CLEANCIDE WIPES EPA Registration No: 34810-36 Application Date: April 23, 2018

Decision Number: 540926

Dear Ms. Kickham,

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, you may contact Lorena Rivas at 703-305-5027 or via email at rivas.lorena@epa.gov.

Sincerely,

Registration Risk Manager Regulatory Management Branch II Antimicrobials Division (7510P) Office of Pesticide Programs

Enclose: Notification Stamped Label

#### [CLEANCIDE WIPES] [READY TO USE]

### [GERMICIDAL DETERGENT]

## [CLEANS] • [DISINFECTS] •[ DEODORIZES] [GERMICIDAL], [PSEUDOMONACIDAL], [TUBERCULOCIDAL], [FUNGICIDAL] and [VIRUCIDAL\*]

NOTIFICATION

ACTIVE INGREDIENT:		34810-36
Citric Acid	0.60%	The applicant has certified that no changes, other than those reported to
OTHER INGREDIENTS:	<u>99.40%</u>	the Agency have been made to the
TOTAL	100.00%	labeling. The Agency acknowledges this notification by letter dated:
		10/02/2018

## 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: 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

#### **Efficacy Claims**

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

[GERMICIDAL:] [Bactericidal] [Bactericidal Activity]

[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-IIIB] (HIV-1) (AIDS Virus)]

[Influenza A Virus [Strain Hong Kong][H3N2]]

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

[Respiratory Syncytial Virus [RSV]]

[Rotavirus]

[Vaccinia Virus]

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

#### [FUNGICIDAL:]

[In the presence of 5% blood serum and a] contact time of 5 minutes, is effective against: [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 tuberculosis [Mycobacterium bovis] [BCG] [Organon Teknika Corp.] [in 5 minutes] [at 20°C / 68°F on previously cleaned hard non-porous inanimate surfaces.]

#### **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 [99.9][9] % of (household) germs
- Suitable for cleaning and deodorizing HVAC air ducts and vents
- Quick and easy cleaning
- Botanical
- Botanical Cleaning
- Botanical ingredient[s]
- Botanically derived ingredient[s]
- Botanical active ingredient
- · Botanically derived active ingredient
- [Botanically based] product]
- 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 simple to use and can help clean up life's everyday messes
- Everyday Cleaner
- Inspired by nature
- Disinfecting Wipe
- Disinfectant Wipe
- One Step
- [Fights] [Effective Against] [Kills] [99.9][9] % of Bacteria
- [Fights] [Effective Against] [Kills] [99.9][9] % of] Viruses\*
- Broad Spectrum Germicide
- No haze
- [Virtually] [haze-free] [film-free] [residue-free shine [clean]
- [Low-haze] [Low-Residue] [Low-Film] [No-Film [Clear-Drying] [Formula] [Wipe] clean[s] thoroughly
- For plastic and painted surfaces, spot test on an inconspicuous area before use.
- [This product or product name] will not harm most surfaces: including acrylic, sealed fiberglass and vinyl.
- Do not use on unpainted wood.
- Note: Do not use on unpainted wood or natural marble or brass.
- For plastic and painted surfaces, spot test on an inconspicuous area before use.
- Do not use as a diaper wipe or for personal cleansing.
- This is not a baby wipe!
- Do not flush [in toilet].
- No Rinse required
- Rinse free [formula]
- No Rinse
- No Rinse Formula
- Rinse Free Formula
- No Rinse Disinfectant
- Kills cold & flu\*
- Kills [cold] [&] [flu] viruses\*
- [Kill[s]] [Remove[s]] [Effective against] [the following] [organisms:]
  - o [the virus that causes the flu] [flu virus][Influenza A2]
  - o [Avian Influenza A] [(H3N2)] [virus] [(Avian Reassortant)]
  - o [Human Immunodeficiency Virus type 1] [HIV-1]
  - o [Pseudomonas] [Pseudomonas aeruginosa] [(ATCC 15442)]
  - o [the viruses\* that causes the cold] [cold virus\*] [Rhinovirus type 37]
  - o [Salmonella enterica] [(Salmonella choleraesuis)] [Salmonella] [(ATCC 10708)]

- o [Staph] [Staphylococcus aureus] [(ATCC 6538)]
- [MRSA] [resistant Staph](ATCC 33592)]
- o [Hep[atitis]] B [HBV], [Duck Hepatitis B (DHBV) as surrogate]]
- o [Pandemic 2009 H1N1 Influenza A Virus [formerly called swine flu]][H1N1][Influenza A]
- o [Feline Calicivirus [surrogate for Norovirus]][Norovirus]
- o [Respiratory Syncytial Virus [RSV]][RSV]
- o [Staphylococcus epidermis MRSE [ATCC 51625]][MRSE]
- o [Rotavirus]
- Bleach[-]free
- Paraben[-]free
- Phenol[-]free
- Does not contain [bleach] [ammonia] [chlorine]
- Does not contain [Triclosan] [Parabens]
- [Contains no] [Does not contain] [bleach,] [added dyes,] [added colors,] [perfumes,] [(volatile organic compounds)], [ammonia], [phosphates], [phosphorus], [chlorine bleach], [dyes], [synthetic fragrances,] [volatile solvents,] [known or suspected endocrine disruptors,] [glycol ethers,][chlorinated compounds,] [or] [chlorine]
- [One step cleaning -and/or- disinfecting -and/or- deodorizing]
- [Disinfect -and/or- touch-up clean] [Cleans -and/or- disinfects -and/or- deodorizes] [In one easy step]
- Kills [over] [99.9][9] % of [household germs] [kitchen germs] [bathroom germs] [germs\*] [,] [botanically] [on hard, non[-]porous surfaces]
- Tough on [dirt] [germs], easy on you.
- Clean without a [harsh] [strong] chemical[s]
- [Can be used] around kids and pets
- Will not damage hard, non[-]porous surfaces

#### <<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].

#### **Optional Fragrance Descriptors:**

- Fresh Lemon Scent
- Apple
- Apple Blossoms
- Arctic breeze
- Bramley Apple Blossom
- Cherry
- Citrus
- Citrus Burst
- Citrus Fresh
- Citrus Splash
- Clean and Fresh
- Clean Mint
- Clean Sparkle
- Cleanmint
- Cool Mint
- Cotton Breeze
- Cotton Lily
- Crystal Clean
- Crystal Mint
- Cucumber Sage
- Dye and Fragrance free
- Floral
- Floral Woods
- 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 Breeze

- Lemon Ginger Reed
- Lemon Verbena
- Lemon Ylang
- Lemon Ylang Flower
- Lime Blossom
- Mandarin Green Tea
- Mint
- Mountain Green
- Ocean Breeze
- Orange
- Orange Fresh
- Orange Mango
- Orange Mango Lily
- Orange Zest
- Outdoor Fresh
- Pacific Rose Apple
- Peach
- Pear
- Pine
- Pink Grapefruit
- Ruby Red Grapefruit
- Scent Free
- Strawberry
- Sweet Pea
- Sweet Pea Bloom
- 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. Preclean areas with gross filth and 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 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.] **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.

#### **USAGE CLAIMS**

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

#### [AREAS OF USE:]

[Athletic Facilities] [Kennels] [Bathrooms] [Kitchens]

[Classrooms] [Laboratories or other small animal facilities]

[Day care centers][Locker Rooms][Dental offices][Medical Offices][Grocery Stores][Nurseries][Grooming Facilities][Nursing homes]

[Gyms] [Schools]

[Health Care Facilities] [Shopping Centers]

[Hospitals] [Spas]

[Institutional facilities] [Veterinary Clinics]

[Institutions]

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

[On washable hard, nonporous surfaces of:]

[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][Bed railings][Obstetrical equipment surfaces][Beds][Operating room lights/tables]

[Blood pressure devices] [Ophthalmic equipment surfaces/devices] [Optical wear (excluding contact lenses)]

[Car Interiors][Oxygen hoods][Chairs][Patient bed surfaces][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] [PPE (Personal Protective Equipment)]

[CPR manikens] [Radiology equipment surfaces] [CT equipment/surfaces] [Refrigerators (exterior surface)]

[Curing lights] [Respirators]

[CuVerro® antimicrobial copper] [Respiratory care equipment surfaces]

[Sealed Granite]
[Shopping carts]
[Shower floors/walls]

[Doorknobs] [Sinks]

[Dental equipment surfaces/devices]

[Desks]

[Exam tables] [Skin care equipment/surfaces]

[Exercise equipment] [Soaking containers] [Fixtures] [Stainless Steel]

[Floors] [Stalls]

[Furniture] [Surgical equipment surfaces] [Surgical microscopes]

[Glass][Tables][Glazed ceramic tile][Telephones][Glazed porcelain][Toilet Seats]

[Handrailings] [Toilets (rims, seats and exterior surfaces)]

[Highchairs] [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]

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 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. 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 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:** 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.

EPA Reg. No. 34810-36

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

[Made in (*insert country*)] [Barcode]

SDS #: [insert SDS number here] Reorder #: [insert reorder number here]

Revised: 01/31/18

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







# THE FOLLOWING OPTIONAL LANGUAGE AND GRAPHICS ARE AVAILABLE FOR USE BY APPROVED SUBREGISTRANTS









Factory Certified







































#### {Optional graphics}









#### TO OPEN:

- 1. Cut off top of pouch with scissors.
- 2. Remove wipes from pouch.
- 3. Place wipes in plastic tub.
- 4. Discard empty pouch into trash.

#### TO USE WITH MOP:

- 1. Unfold top wipe in tub by pulling sides of the cloth over edges of tub.
- 2. Place sweeper on head.
- 3. Wrap wipe around head of sweeper.
- 4. Push edges of wipe into top of sweeper head.
- 5. Begin wiping. No rinsing required.
- 6. After use, remove soiled wipe and discard in trash. Do not flush.















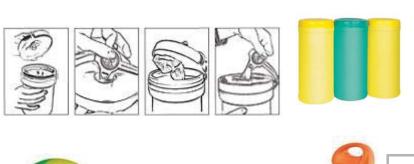
Note to reviewer: Representative graphic of wipe tub and/or hand pulling out wipe fabric may be added to the final printed label.

Note to reviewer: A representative graphic of a substrate may be added to the label. Only a graphic of the substrate actually in the canister can be added to the final printed label.





{Note to reviewer: the graphic to the left denotes a picture of a substrate. It will only be added to the final printed label if this substrate is actually in the canister can.}















#### TO OPEN PACKAGE:

- Flip open dispensing cap and remove entire lid from canister by lifting upward.
- Locate wipe at center of roll, twist corner to a point and thread through small opening in lid. DO NOT PUSH FINGER THROUGH OPENING.
- Replace lid and pull sheet up at an angle. Remaining wipes feed automatically.
- When finished, snap lid cap shut to retain moisture.









[graphic depicting outdoor fresh scent]





















Wind Energy logo™ is a trademark of U.S. Nonwovens Corp. All rights reserved.

[Made with 100% Clean Wind Energy]