



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 21, 2017

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

Subject: Notification per PRN 98-10 – Add alternate dispenser directions, logo, & graphics
Product Name: WEXFORD DISINFECTANT WIPES
EPA Registration Number: 34810-37
Application Date: 02-Aug-2017
Decision Number: 532354

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.

If you have any questions, you may contact Tiffany Tran at 703.347.0414 or via email at Tran.Tiffany@epa.gov.

Sincerely,

A handwritten signature in red ink that reads "Jacqueline Hardy".

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

**WEXFORD DISINFECTANT WIPES
[READY TO USE]
[GERMICIDAL DETERGENT]
[CLEANS] • [DISINFECTS] • [DEODORIZES]
[GERMICIDAL], [PSEUDOMONACIDAL], [TUBERCULOCIDAL],
[FUNGICIDAL] and [VIRUCIDAL*]**

NOTIFICATION

ACTIVE INGREDIENT:

Citric Acid 0.60%

OTHER INGREDIENTS: 99.40%

Includes biodegradable detergents

TOTAL 100.00%

34810-37

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:

08/21/2017

EPA Reg. No. 34810-37 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_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")

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]
- [Broad Spectrum Hospital Disinfectant]
- [Disinfecting Wipe]
- [Disinfectant Wipe]
- [One Step]

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. 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.]

Or



[Flip open lid. To remove first wipe pull up on wipe and remove wipe through wavy dispensing opening. The next wipe will pop up automatically. Always snap lid securely between uses to retain moisture.]

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 Wexford Disinfectant Wipes 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]
Dialysis Units	[Kitchens]
[Dental offices]	[Institutional facilities]
[Day care centers]	[Kennels]
[Nurseries]	[Grooming Facilities]
[Schools]	[Veterinary Clinics]
[Laboratories or other small animal facilities]	

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

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]
[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]	[Shower floors/walls]
[Doorknobs]	[Sinks]
[Exam tables]	[Skin care equipment/surfaces]
[Exercise equipment]	[Soaking containers]
[Fixtures]	[Stainless Steel]
[Floors]	[Stalls]
[Furniture]	[Surgical equipment surfaces]
[Garbage cans]	[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

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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.

***WEXFORD DISINFECTANT WIPES 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: Leave precleaned surfaces wet for five minutes 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 Wexford Disinfectant Wipes 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.

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

[Made in (insert country)]

[Barcode]

MSDS #: xxxxx

Reorder #: xxxx-xx

Revised: 07/28/2017

[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



*LemiShine (Supplemental Registrant)
Company Logo*

