

34810-37

6/27/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

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ASHIN

JUN 27 2013

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

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTI

Subject: **Wexford Disinfectant Wipes**
EPA Registration No. 34810-37
Application Date: February 8, 2013
Receipt Date: February 11, 2013

Dear Ms. Auer:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3 (c) 7 A as amended, is acceptable.

Proposed Amendment:

- Adding DfE Logo on Label
- Adding optional marketing language, surfaces and use sites

General Comments

A stamped label is enclosed for your records. Submit (1) one final printed label bearing the revised labeling prior to selling or distributing the product.

The Confidential Statement of Formula (CSF) dated, February 8, 2013 for the basic and alternate formulations #1, is acceptable and found to be in compliance with PR Notice 91-2 and in agreement with the label.

Should you have any questions concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by email at grigsby.stacey@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacqueline Hardy".

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

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

ACTIVE INGREDIENT:	
Citric Acid	0.60%
OTHER INGREDIENTS:	
	<u>99.40%</u>
Includes biodegradable detergents	
TOTAL	100.00%

EPA Reg. No. 34810-37 EPA Est. No. XXXXXXXX

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

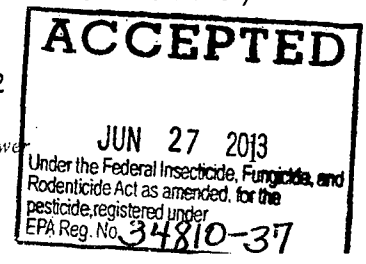
IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing. Call a Poison Control Center or doctor for further treatment advice.

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

Note to reviewer: Language in [] is optional or interchangeable; red italics are registrant's comments to Reviewer



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]

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]	

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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.

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] | |

[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] |

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- [Cabinets]
- [Chairs]
- [Changing tables]
- [Children's toys]
- [Chrome]
- [Computer surfaces]
- [Computers]
- [Counters]
- [Countertops]
- [CPR manikens]
- [CT equipment/surfaces]
- [Curing lights]
- [CuVerro, antimicrobial copper]
- [Dental equipment surfaces/devices]
- [Doorknobs]
- [Exam tables]
- [Exercise equipment]
- [Fixtures]
- [Floors]
- [Furniture]
- [Garbage cans]
- [Glass]
- [Glazed ceramic tile]
- [Glazed porcelain]
- [Handrailings]
- [Highchairs]
- [Immobilization devices]
- [Infant care equipment]
- [Isolettes]
- [Keyboards]
- [Kitchen surfaces]
- [Laboratory equipment/surfaces]
- [Light lens covers]
- [Lights]
- [Optical wear (excluding contact lenses)]
- [Oxygen hoods]
- [Patient bed surfaces]
- [Patient transport surfaces]
- [Pet Habitats]
- [Physical therapy equipment]
- [Plastic]
- [Play mats]
- [Play-care equipment]
- [Radiology equipment surfaces]
- [Refrigerators (exterior surface)]
- [Respirators]
- [Respiratory care equipment surfaces]
- [Shower floors/walls]
- [Sinks]
- [Skin care equipment/surfaces]
- [Soaking containers]
- [Stainless Steel]
- [Stalls]
- [Surgical equipment surfaces]
- [Surgical microscopes]
- [Tables]
- [Telephones]
- [Toilet Seats]
- [Toilets (rims, seats and exterior surfaces)]
- [Toys]
- [Training tables]
- [Transportation equipment surfaces]
- [Trays]
- [Vinyl]
- [Walls]
- [Work stations]
- [Wrestling mats]
- [X-ray equipment/surfaces]

xygen
 Patient
 Patient
 Pet Ha
 Physi
 Plastic

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.

***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 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 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: 02/08/2013

[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

