

34810-36

02-02-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

FEB - 2 2010

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

Subject: **CleanCide Wipes**
EPA Registration No. 34810-36
Amendment Date: June 23, 2009
EPA Receipt Date: September 17, 2009

Dear Ms. Auer:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) is acceptable with the conditions below.

Proposed Amendment

- Addition of Hepatitis C Virus (HCV) claim to the label
- Submission of Efficacy Data for review

Conditions

Revise the label as follows:

1. Revise the third sentence after "CAUTION:" in the **Precautionary Statements** section to read as follows: "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."
2. Revise the "Personal Protection:" language (bottom of page 2) under the **Special Instructions for Cleaning and Decontaminating Surfaces/Objects Soiled with Blood and Body Fluids Which May Contain HBV, HCV and HIV-1 (AIDS virus)**: to read as follows, "When handling objects soiled with blood or body fluids use disposable latex gloves, gowns, mask *and* eye coverings."
3. The second to last section of page 3 (**Disposal of Infectious Material**) must be moved below the **Special Instructions for Cleaning and Decontaminating Surfaces/Objects Soiled with Blood and Body Fluids Which May Contain HBV, HCV and HIV-1 (AIDS virus)**: section so that the disposal instructions for infectious material are

immediately after the special instructions for cleaning and decontaminating. In other words, the **Disposal of Infectious Material** section must be moved above the **Veterinary Practice/Animal Care/Animal Laboratory/Zoos/Pet Shop/Kennels Disinfection Directions:** section.

Efficacy

The following efficacy studies were submitted in support of this product:

Study	MRID Number	Study Status
Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus	47619401	Acceptable
Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus – Confirmatory Assay	47619402	Acceptable

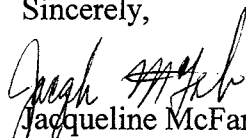
General Comments

A stamped copy of the accepted labeling with conditions is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Heather Garvie at (703) 308-0034 or by email at garvie.heather@epa.gov or Jacquie McFarlane at (703) 308-6416.

Sincerely,



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

Enclosures: Stamped label; and Efficacy Review (DP Barcode #: D370269)
7510P: H.Garvie: February 2, 2010: 34810-36 relying on new data

ACCEPTED
with COMMENTS
in EPA Letter Dated:

CLEAN-CIDE WIPES
Cleans, Disinfects, Deodorizes
Germicidal, Fungicidal, and Virucidal*

FEB 2 2010
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **34810-36**

Active Ingredient: Citric Acid 0.6%
Inert Ingredients: 99.4%
Includes biodegradable detergents
Total: 100.0%

EPA Reg. No. 34810-36

EPA Est. No. 34810-MO-1

KEEP OUT OF REACH OF CHILDREN
CAUTION

Effective in 5% serum against:

GERMICIDAL: *Pseudomonas aeruginosa*¹ [ATCC 15442], *Staphylococcus aureus*¹ [ATCC 6538], *Salmonella enterica*¹ (formerly *Salmonella Choleraesuis*) [ATCC 10708], *Listeria monocytogenes*¹ [ATCC 19117], *Escherichia Coli O157:H7*¹ [ATCC 43888], *Staphylococcus aureus* - MRSA¹ [ATCC 33592], *Staphylococcus epidermis* - MRSE¹ [ATCC 51625], *Enterococcus faecalis* Vancomycin Resistant¹ (VRE) [ATCC 51575], *Acinetobacter baumannii*² [ATCC 19606] **VIRUCIDAL:** Poliovirus² type 1, Canine Parvovirus² (CPV), Respiratory Syncytial Virus¹, Rotavirus¹, Human Immunodeficiency Virus¹ Type 1 (Strain HTLV-III_B), Herpes Simplex¹ Type 1, Herpes Simplex¹ Type 2 (Strain G), Vaccinia Virus¹, Influenza A Virus¹ (Strain Hong Kong), Adenovirus¹ Type 2, Duck Hepatitis B Virus (DHBV)², Hepatitis C (HCV)² (utilizing Bovine Viral Diarrhea Virus as a surrogate for Human Hepatitis C), Feline Calicivirus¹ (surrogate for Norovirus) **FUNGICIDAL:** *Trichophyton mentagrophytes*² [ATCC 9533]

- 1 - Five minutes Contact Time
- 2 - Ten minutes Contact Time

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.

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.

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

NET CONTENTS: X lbs, X oz.

X Pre-moistened Towelettes (X)" x (X)"
(e.g. 100 Pre- moistened Towelettes 7"x 8")

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.

DISPENSER DIRECTIONS: Wear gloves. 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.

TO DISINFECT: Unfold premoistened cloth and wipe area to be cleaned and disinfected. Use enough wipes for treated surface to remain visibly wet for 10 minutes. Wipe or let air dry. For gross filth or heavy soil, use a wipe to clean and then a second wipe to disinfect the surface. **DO NOT MIX WITH OTHER CLEANERS.**

[AREAS OF USE:]

- | | |
|---|----------------------------|
| [Hospitals] | [Bathrooms] |
| [Health Care Facilities] | [Institutions] |
| [Medical Offices] | [Institutional facilities] |
| [Dental offices] | [Veterinary Clinics] |
| [Day care centers] | [Kennels] |
| [Nurseries] | [Grooming Facilities] |
| [Schools] | [Zoos] |
| [Nursing homes] | [Pet Shops] |
| [Laboratories or other small animal facilities] | |

[TYPES OF SURFACES:]

- [On washable hard, nonporous surfaces of:]
- | | |
|---------------------|-------------------|
| [Bathroom fixtures] | [Stainless Steel] |
| [Floors] | [Chrome] |
| [Walls] | [Glass] |
| [Vinyl] | |

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.

***CLEAN-CIDE WIPES KILLS HBV, HCV and 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 Hepatitis B Virus, Hepatitis C Virus and 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 ██████████ AND HIV-1 (AIDS virus):

Personal Protection: When handling objects soiled with blood or body fluids use disposable latex gloves, gowns, mask, or eye coverings.

Cleaning Procedure: All blood and body fluids must be cleaned from surfaces before disinfection by the germicidal cloth. Use one germicidal cloth to remove gross soil.

Contact Time: Use a second germicidal cloth to thoroughly wet surface. Allow to remain wet 5 minutes for HIV-1, 10 minutes for HBV and HCV, let air dry.

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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. Unfold premoistened cloth and wipe area to be cleaned and disinfected. Use enough wipes for treated surface to remain visibly wet for 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.

Disposal of Infectious Material: Dispose of used towelette in accordance with local regulations for infectious waste disposal.

STORAGE AND DISPOSAL: Store in a cool place. Do not leave containers open during storage. Do not reuse empty container. No special handling is required. Dispose of used towelette in accordance with Federal, State, or local regulations for infectious waste disposal.

Made in the USA

MSDS #: 3130-XX

Reorder #: 3130-XX