

U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Antimicrobials Division (7510C)
 1200 Pennsylvania Avenue NW
 Washington, D.C. 20460

EPA Reg. Number:
34810-36

Date of Issuance:
March 3, 2006



NOTICE OF PESTICIDE:
 Registration
 Reregistration

Term of Issuance:
Conditional

Name of Pesticide Product:
Clean Cide-Wipe

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

**Wexford Labs, Inc.
 325 Leffingwell Avenue
 Kirkwood, MO 63122**

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

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

2. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration Number 34810-36".

Signature of Approving Official:

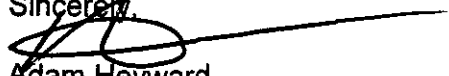

 Adam Heyward
 Product Manager Team-34
 Regulatory Management Branch II
 Antimicrobials Division (7510C)

Date:

March 3, 2006

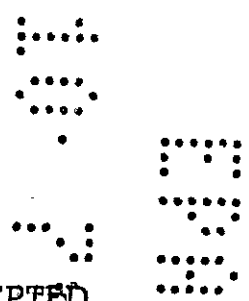
- b. The proposed label does not identify the dimensions of the towelette, or identify the recommended maximum surface area to be treated per towelette. In addition, the label does not state wipe surfaces for 30 seconds (which is the amount of time carriers were wiped during laboratory testing). Finally the label does not state: "Use enough wipes for treated surface to remain visibly wet for the contact time listed on the label". The label must be revised to include the above information.
 - c. In accordance with DIS/TSS-15, label directions regarding use of antimicrobial pesticides on hard surfaces must include the types of surfaces and objects on which the product is recommended for use (e.g., floors, toilets, medical instruments). Revise the product label to include these information, if the product is recommended for objects other than critical and semi-critical medial devices.
 - d. Revise label claims for "*Clostridium difficile*" to read "*Clostridium difficile* (vegetative)". This must also be done on EPA Reg. No. 34810-35.
3. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revises labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Sincerely,

 Adam Heyward
 Product Manager 34
 Regulatory Branch II
 Antimicrobials Division (7510C)

Enclosure: (Stamped Labeling, Product Chemistry and Efficacy DER)

Clean-Cide Wipes
Cleans, Disinfects, Deodorizes
Germicidal, Fungicidal, and Virucidal



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

ACCEPTED
with COMMENTS
EPA Letter Dated:

EPA Reg. No. 34810-

EPA Est. No. 34810-MO-1

KEEP OUT OF REACH OF CHILDREN
CAUTION

MAR - 3 2006

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

FIRST AID

PRECAUTIONARY STATEMENT: HAZARD TO HUMANS AND DOMESTIC ANIMALS. Avoid direct food contact. Avoid eye contact. Immediately flush eyes with water in case of contact. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

GERMICIDAL ACTIVITY: This product is effective in 5% serum against: *Pseudomonas aeruginosa*¹, *Staphylococcus aureus*¹, *Salmonella choleraesuis*¹, *Trichophyton mentagrophytes*¹, *Listeria monocytogenes*¹, *Escherichia coli*¹, *Clostridium difficile*², Poliovirus² type 1, Canine Parvovirus² (Strain Cornell), Respiratory¹ Syncytial virus, Rotavirus¹, Human Immunodeficiency¹ Virus Type 1, *Staphylococcus aureus - MRSA*¹, *Staphylococcus epidermis - MRSE*¹, *Enterococcus faecalis Vancomycin Resistant*¹ (VRE), Herpes Simplex¹ Type 1, Herpes Simplex¹ Type 2, Vaccinia Virus¹, Influenza A Virus¹ (Hong Kong), Adenovirus Type 2¹, Duck Hepatitis B Virus (DHBV)²

1 - Five minutes Contact Time

2 - Ten minutes Contact Time

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 the observance of Federal, State, or local regulations for infectious waste disposal.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Use Clean-Cide Wipes for One-Step cleaning, disinfecting and deodorizing of hard, non-porous surfaces, in areas such as Operating Rooms, Intensive Care areas, Nurseries, Emergency Areas, Patient Rooms, Exam Rooms, Clinics, Dental Operatories, EMS and other emergency response units. Clean-Cide wipes are designed for use on surfaces such as stainless steel, chrome, glass and vinyl. Unfold premoistened cloth and wipe area to be cleaned and disinfected. **Contact time:** 10 minutes. Allow to 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.**

4/4

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.

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.

***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, 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 to inactivate HIV-1. Air dry. (Allow surfaces to remain wet for 10 minutes to inactivate all organisms claimed on this label.)

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

Distributed by:
Wexford Labs, Inc.
325 Leffingwell Avenue
Kirkwood, MO 63122