

34810-35

07/18/2006

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

July 18, 2006

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

Subject: **Clean-Cide**  
EPA Registration No.: 34810-35  
Application Date: June 26, 2006  
Receipt Date: June 27, 2006

Dear Ms. Auer:

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

Proposed Amendment:

Revised Labeling

Other Comments:

- Use the term: "vegetative cells only"
- When using " *M. bovis*" please note the small "b"
- When using " *E. coli* O157:H7" please use as stated here.

General Comment:

A stamped copy of the accepted labeling is enclosed.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or Stacey Grigsby at (703) 305-6440.

Sincerely,

A handwritten signature in cursive script that reads "Stacey Grigsby".

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

**CLEAN-CIDE  
READY TO USE**

GERMICIDAL DETERGENT  
CLEANS • DISINFECTS • DEODORIZES  
GERMICIDAL, PSEUDOMONACIDAL, TUBERCULOCIDAL,  
FUNGICIDAL and VIRUCIDAL\*

ACTIVE INGREDIENT:  
Citric Acid ..... 0.60%  
OTHER INGREDIENTS: ..... 99.40%  
100.00%

EPA Reg. No. 34810-35      EPA Est. No. 34810-MO-1

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

GERMICIDAL: effective in 5% serum against: *Pseudomonas aeruginosa*<sup>1</sup>, *Staphylococcus aureus*<sup>1</sup>, *Salmonella choleraesuis*<sup>1</sup>, *Listeria monocytogenes*<sup>1</sup>, *Escherichia Coli O157:H7*<sup>1</sup>, *Clostridium difficile* - vegetative state<sup>2</sup>, *Staphylococcus aureus* - MRSA<sup>1</sup>, *Staphylococcus epidermis* - MRSE<sup>1</sup>, *Enterococcus faecalis* Vancomycin Resistant<sup>1</sup> (VRE) VIRUCIDAL: effective in 5% serum against: Poliovirus<sup>2</sup> type 1, Canine Parvovirus<sup>2</sup> (CPV), Respiratory Syncytial Virus<sup>1</sup>, Rotavirus<sup>1</sup>, Human Immunodeficiency Virus<sup>1</sup> Type 1 (Strain HTLV-III<sub>B</sub>), Herpes Simplex<sup>1</sup> Type 1, Herpes Simplex<sup>1</sup> Type 2 (Strain G), Vaccinia Virus<sup>1</sup>, Influenza A Virus<sup>1</sup> (Strain Hong Kong), Adenovirus<sup>1</sup> Type 2, Duck Hepatitis B Virus (DHBV)<sup>2</sup> FUNGICIDAL: effective in 5% serum against *Trichophyton mentagrophytes*<sup>2</sup>

1 - Five minute Contact Time    2 - Ten minute Contact Time

TUBERCULOCIDAL: effective against *Mycobacterium bovis* in 5 minutes 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.

**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.

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

Net Contents: One Quart

**CLEAN-CIDE**

**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. **DO NOT DILUTE.** Clean-Cide is a synthetic germicidal detergent with broad spectrum kill of gram positive and gram negative microorganisms. It is an excellent cleaner for working surfaces, such as stainless steel, chrome, glass, and vinyl. Apply with a cloth or brush, or by immersing equipment to disinfect. **CONTACT TIME: 10 Minutes.** For heavily soiled areas or surfaces or objects soiled with blood or body fluids, a precleaning step must be implemented to remove the heavy soil before disinfection. Discard solution when it becomes dirty, replace with fresh solution. **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.

**\*CLEAN-CIDE 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: DO NOT DILUTE** this product. Use as is. Remove and clean blood and other body fluids from surfaces and objects before application of Clean-Cide with a mop, cloth, or sponge so as to thoroughly wet pre-cleaned surfaces. Allow surfaces to remain wet for five minutes to ensure total in-activation of HIV virus. For lightly soiled areas wipe off visual soil, clean with solution, and disinfect surface with second application of solution. For large spills, the contaminated area should be flooded with the solution before cleaning then decontaminated with fresh solution.

**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.

CLEAN-CIDE is a broad spectrum, highly effective disinfectant and cleaner for use on hard, non-porous surfaces of inanimate objects. It is also designed to pre-soak and decontaminate instruments before sterilization. Clean-Cide is useful in the patient care, patient examination, laboratory, and food preparation area (non-food contact surfaces only), of medical, dental, and veterinary clinic and practitioners offices. Clean-Cide can also be used on the hard, non-porous surfaces of long term care facilities where environmental control of cross contamination is important.

**STORAGE AND DISPOSAL:** Store in a cool place. Do not leave containers open during storage. Do not reuse empty container. Wastes resulting from use of this product may be poured down the drain. No special handling is required. Federal, State, or local regulations should be observed.

Made in the USA

Reorder #: 2130-02

ACCEPTED MSDS #: 2130-02

with COMMENTS  
EPA label dated:

JUL 18 2006

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the purpose, registered under EPA Reg. No. 34810-35

Rev062606

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