 <b>U.S. ENVIRONMENTAL PROTECTION AGENCY</b> Office of Pesticide Programs Antimicrobials Division (7510C) 1200 Pennsylvania Avenue NW Washington, D.C. 20460	EPA Reg. Number: <b>34810-35</b>	Date of Issuance: <b>August 10, 2005</b>
	Term of Issuance: <b>Conditional</b>	
	Name of Pesticide Product: <b>Ultra-Cide Ready To Use</b>	

NOTICE OF PESTICIDE:  
  x   Registration  
      Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):  
**Wexford Labs, Inc.**  
**325 Leffingwell Avenue**  
**Kirkwood, MI 63122**

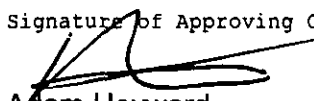
Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

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 re-registration 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 34810-35".

Signature of Approving Official:  <b>Adam Heyward</b> Product Manager Team-34 Regulatory Management Branch II Antimicrobials Division (7510C)	Date:  <b>August 10, 2005</b>
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- b. Delete the claim for "Tuberculocidal" from the label. The claim is not supported by the data submitted.
- c. In the effort to suppress multiple contact times for disinfection uses of a product, the Agency adopted "**one contact time**" approach for efficacy reasons. The product **Ultra-Cide Ready to Use** can only be used for 10 minutes contact time. Therefore, the label must list only one contact time, which is 10 minutes.
- d. The net content must be listed on the label.
- e. The appropriate signal word is "CAUTION".
- f. Add the following precautionary statements to the label:

Precautionary Statements  
Hazards to Humans and Domestic Animals

Caution: "Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

- g. The First Aid statements must be revised to state:

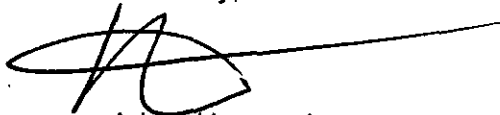
**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing. Call a Poison Control Center or doctor for further treatment advice.

- 3. Submit three (3) copies of the final printed label prior to releasing this product for sale.

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.

A stamped copy of the label is enclosed for your records.

Sincerely,



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

Enclosure: (Stamped Label and review DERs)

**ULTRA-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-GL

EPA Est. No. 34810-MO-1

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**FIRST AID**

**FOR SKIN.** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Have the product container or label with you when calling the doctor. **PRECAUTIONARY STATEMENTS: HAZARD TO HUMANS AND DOMESTIC ANIMALS. CAUTION:** Avoid contact with eyes, skin or clothing. 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*<sup>1</sup> (ATCC 15442), *Staphylococcus aureus*<sup>1</sup> (ATCC 6538), *Salmonella choleraesuis*<sup>1</sup> (ATCC 10708), *Trichophyton mentagrophytes*<sup>1</sup> (ATCC 9533), *Listeria monocytogenes*<sup>1</sup> (ATCC 19117), *Escherichia Coli*<sup>1</sup> (ATCC 43888), *Mycobacterium bovis*<sup>3</sup> - BCG (Organon Teknika #105401), *Clostridium difficile*<sup>2</sup> (ATCC 9689), Poliovirus<sup>2</sup> type 1 (ATCC VR-58, Strain Brunhilde), Canine Parvovirus<sup>2</sup> (CPV), (ATCC VR-2017, Strain Cornell), Respiratory<sup>1</sup> Syncytial virus (ATCC VR-26, Strain Long), Rotavirus<sup>1</sup> (Strain WA, University of Ottawa), Human Immunodeficiency<sup>1</sup> Virus Type 1, (Strain HTLV-III<sub>B</sub>), *Staphylococcus aureus* - MRSA<sup>1</sup> (ATCC 33592), *Staphylococcus epidermis* - MRSE<sup>1</sup> (ATCC 51625), *Enterococcus faecalis* Vancomycin<sup>1</sup> Resistant (ATCC 51575), Herpes Simplex<sup>1</sup> Type 1 (ATCC VR-733, Strain F(1)), Herpes Simplex<sup>1</sup> Type 2 (ATCC VR-734, Strain G), Vaccinia<sup>1</sup> Virus (ATCC VR-119, Strain WR), Influenza<sup>1</sup> A Virus (ATCC VR-544, Strain Hong Kong), Adenovirus type 2 (ATCC VR-846, Strain Adenoid 6)<sup>1</sup>, Duck Hepatitis B Virus (DHBV)<sup>2</sup>

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

**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.

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

Contents: One Quart

**ACCEPTED**  
 with **COMMENTS**  
 EPA Letter Dated:

**AUG 10 2005**

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

**ULTRA-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.** Note contact time for individual microorganisms on this label before wiping. Ultra-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. 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

**\*ULTRA-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 Ultra-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.

**ULTRA-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. Ultra-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. Ultra-Cide can also be used on the hard, non-porous surfaces of long term care facilities where environmental control of cross contamination is important

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3/3