

T.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Program Registration Division (H7505C) 401 "M" St., S.W. Washington, D.C. 20460

EPA Req. Number:

Date of Issuance:

34810-25

SEP 12 2001

Term of Issuance:

NOTICE OF PESTICIDE:

\_\_\_ Registration

X \_ Reregistration

(under FIFRA, as amended)

Name of Pesticide Product:

Ready To Use Thymo-Cide

Name and Address of Registrant (include ZIP Code):

Wexford Labs, Inc. 325 Leffingwell Avenue Kirkwood, Missouri 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 Rogenticide 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 connectics with the registration of a product under this Act is not to be construen as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

Based on your response to the Reregistration Eligibility Document, EPA has reregistered the above named product subject to the comments recorded in the succeeding paragraph. This action is taken under the authority of section 4(q)(2)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of you product.

Make the following labeling changes before you release the product for shipment:

1. The word "biodegradable" under the ingredient statement must be deleted from the label. This term is unacceptable for any pesticide product. The term may be used only in reference to the package or packaging and then only if you certify that the package does break down and you provide information to support it.

Signature of Approving Official:

Adam Heyward

SEP 12 2001

Product Manager 34

RMB'II/Antimicrobials Division

- 2. The use directions must include the types of hard surfaces, such as floors, walls, tables etc. The statement all types is too broad.
- 3. Add the statement "Do not use on food contact surfaces."
- 4. Submit five (5) copies of your final printed labeling before you release the product for shipment.

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

If these 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 constitutes acceptance of these conditions.

Sincerely yours,

Adam Heyward

Product Manager 34

Regulatory Management Branch II Antimicrobials Division (H7510W)

Enclosure

## "READY TO USE THYMO-CIDE"

# GERMICIDAL DETERGENT CLEANS • DISINFECTS • DEODORIZES GERMICIDAL, PSEUDOMONACIDAL, TUBERCULOCIDAL FUNGICIDAL and VIRUCIDAL\* with 5% Serum.

EPA REG. NO. 34810-25 ● EPA EST, NO. 34810-MO-1

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### FIRST AID

FOR SKIN: Take off contaminated clothing. Rinse stin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

PRECAUTIONARY STATEMENTS: HAZARD TO HUMANS AND DOMESTIC ANIMALS.

PRECAUTIONARY STATEMENTS: HAZARD TO HUMANS AND DOMESTIC ANIMALS. CAUTION: Harmful if absorbed through akin. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

STORAGE and DISPOSAL: Store at room temperature. Do not leave containers of this product open during storage. Do not reuse empty container. Rinse thoroughly, Wrap container and put in trash. Waste resulting from the use of this product may be disposed of according to applicable Federal. State or local procedures.

GERMICIDAL ACTIVITY: (AOAC Use Dilution Confirmation in the presence of 5% serum.) Ps. aeruginosa, S. aureus, S. choleraesuis; including S. aureus (MRSA) (TNSR) (GRM) and (PR) and S. Epidermidis (MRSE), TUBERCULOCIDAL ACTIVITY: (AOAC M. tuberculosis in the presence of 5% serum at 20°C for 10 minutes) FUNDICIDAL ACTIVITY: (AOAC T. Mentagrophytes in the presence of 5% serum.) VIRUCIDAL ACTIVITY: (\*Influenza A3[\*tong Kong], Herpes simplex Types 2, Vaccinia virus in the presence of 5% serum, and HIV-1 [AIOS] in the presence of 10% serum on inanimate surfaces.



### Wexford Labs, Inc.

325 Leffingwell Avenue . Kirkwood, Missouri 63122

Cordents; On Quart

ACCEPTED

with COMMENTS in EPA Letter Dated:

SEP 1 2 2001

Under the Federal Insecticide,
Pungicide, and Roder to the Act as
amended, for the periodes,
registered under EPA Res. No. 348 10-25

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Use Ready To Use Thymo-Cide for all disinfection of hard, inanimate surfaces, in Operating Rooms, intensive Care, Nurseries, Emergency Areas, Dental Operatories, Police, EMS, all health care facilities. It is a synthetic germicidal detergent with broad spectrum kill of gram positive and gram negative microrganisms, and an excellent cleaner for working surfaces, stainless steel, chrome, glass and vinyl. Apply with a cloth or brush, or by immersing equipment to be disinfected. All hard surfaces must be wet thoroughly, and remain wet for at least 10 minutes before drying with a cloth. Gross filth and heavy soil must be removed before applying cleaning solution. Discard solution when it becomes dirty, replace with fresh solution. DO NOT MIX WITH OTHER CLEANERS.

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.

\*READY TO USE THYMO-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 inanimate 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: Wear disposable rubber or latex gloves, gowns, face masks, or eye coverings as appropriate, when performing manual cleaning of these surfaces. CONTACT TIME: Leave surfaces wet for 1 minute. This contact time will not control other common types of viruses and bacteria. CLEANING PROCEDURE: The solution may be used to remove and clean blood and other body fluids from surfaces and objects before disinfection. For lightly soiled areas wipe off visual soil/clean with solution, and disinfect surface with a second application of the 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 body fluids should be autoclaved and disposed of according to Federal State and local regulations for infectious waste disposal.

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24