

34810-25

12-17-2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

December 17, 2002

Mr. Said I, Raziq
Director of Research
WEXFORD Labs, Inc.
325 Leffingwell Avenue
Kirkwood, MO 63122

Subject: Ready to Use Thymo-Cide
EPA Registration Number 34810-25
Letters Dated July 29, 2002

Dear Mr. Raziq:

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

Proposed Amendment

- data to support new label claims

Acceptable data:

The submitted efficacy data (MRID No. 457270-01) supports the use of the subject product as a disinfectant with bactericidal activity when tested against *Enterococcus faecalis* - VRE in the presence of a 5% organic soil load (fetal bovine serum) on hard, non-porous surfaces for a contact time of 10 minutes.

Th submitted efficacy data supports the use of the subject product as a disinfectant with virucidal activity when tested against the microorganisms Respiratory syncytial virus (MRID No. 457270-02) and Rotavirus (MRID No. 457270-03) in the presence of a 5% organic soil load (fetal bovine serum) on hard, non-porous surfaces for a contact time of 10 minutes.

CONCURRENCES

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Labeling comments:

The following label revisions must be made:

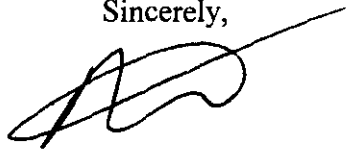
1. The label uses the term “hard, inanimate surfaces” in the Directions for Use. The Agency terminology is “hard, non-porous surfaces.” The two words underlined are not synonymous. Directions must specify use on use on non-porous surfaces.
2. In listing the organisms for which efficacy of the product as a disinfectant against the organism *Staphylococcus aureus* is claimed, qualifying terms such as “(MRSA), (TNSR), (GRM), and (PB)” are used. Current usage still accepts the MRSA designation to indicate the organism is resistant to the action of the antibiotic methicillin. The other terms are not currently used and are not self-explanatory about the present status of resistance of the organism *Staphylococcus aureus*. Therefore, you must delete the terms “TNSR, GRM, and PB from the product labeling.”
3. Revise the first aid statement in accordance with PR Notice 2001-1

For detailed information and consideration, refer to the enclosed efficacy review dated October 28, 2002.

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Drusilla Copeland at (703) 308-6224.

Sincerely,



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

Enclosure

READY TO USE THYMO-CIDE

GERMICIDAL DETERGENT

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

ACTIVE INGREDIENT:	
Thymol	0.051%
INERT INGREDIENTS:	
Includes detergents, perfume and water	99.949%
EPA REG. NO. 34810-25 • EPA EST. NO. 34810-MO-1	100.000%

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. 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.

CAUTION: Harmful if absorbed through skin. 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). Enterococcus Faecalis (FRE). **TUBERCULOCIDAL ACTIVITY:** (AOAC M. tuberculosis in the presence of 5% serum at 20°C for 10 minutes) **FUNGICIDAL ACTIVITY:** (AOAC T. Mentagrophytes in the presence of 5% serum.) **VIRUCIDAL ACTIVITY:** (*Influenza A3(Hong Kong), Herpes simplex Types 2, Vaccinia virus, Human Rotavirus, and Respiratory syncytial virus in the presence of 5% serum, and HIV-1 (AIDS) in the presence of 10% serum on inanimale surfaces.



Wexford Labs, Inc.

325 Leffingwell Avenue • Kirkwood, Missouri 63122

Contents: One Quart

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, (floors, walls, tables, etc.) in Operating Rooms, Intensive Care, Nurseries, Emergency Areas, Dental Operatories, Police, EMS, all health care facilities. Do not use on food contact surfaces. Ready To Use Thymo-Cide is a synthetic germicidal detergent with broad spectrum kill of gram positive and gram negative microorganisms, 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.

ACCEPTED
with COMMENTS
EPA Letter Dated:

DEC 17 2002

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 34810-25

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