

FILED 34810-25
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 6 1995

WEXFORD LABS, INC.
325 Leffingwell Avenue
Kirkwood, MO 63122

Attention: Said I. Raziq
Director of Research

Subject: Ready to Use Thymo-cide
EPA Registration No. 34810-25
MOU Compliance Amendment dated July 31, 1995

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, will be acceptable provided that you make the labeling change listed below before you release the product for shipment bearing the amended label.

1. Remove surgical instruments from the list of surfaces to be disinfected. Surgical instruments are critical medical devices and must be sterilized.

A stamped copy is enclosed for your records. Submit five (5) copies of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely,



Ruth G. Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 6 1995

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

34810-25

READY TO USE THYMO-CIDE GERMICIDAL DETERGENT

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

ACTIVE INGREDIENT:
5-Methyl-2-isopropyl-1-phenol 0.051%
INERT INGREDIENTS: 99.949%
Includes biodegradable detergents, perfume and water 100.000%

EPA REG. NO. 34810-25 • EPA EST. NO. 34810-MO-1

KEEP OUT OF REACH OF CHILDREN
CAUTION

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) FUNGICIDAL ACTIVITY: (AOAC T. Mentagrophytes in the presence of 5% serum.) VIRUCIDAL ACTIVITY: (*Influenza A3(Hong Kong), Herpes simplex Types 2, Vaccinia virus in the presence of 5% serum, and HIV-1 [AIDS] in the presence of 10% serum on inanimate surfaces)

Use: READY TO USE THYMO-CIDE for all disinfection of hard, non-porous, inanimate surfaces in Operating Rooms, Intensive Care, Nurseries, Emergency Areas and Dental Operatories, as well as Police, EMS and other emergency response units. It is a synthetic germicidal detergent with broad spectrum kill of gram positive and gram negative microorganisms. It is an excellent cleaner.

STORAGE and DISPOSAL: Store at room temperature. Do not leave containers of this product open during storage. Do not reuse empty container. Rinse empty container thoroughly and discard in trash.



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 label. Use: READY TO USE THYMO-CIDE for all disinfection of hard, inanimate surfaces, facilities, for working surfaces, surgical instruments, stainless steel, chrome, glass and plastic, by brushing, or by immersing equipment to be disinfected. All hard surfaces must be wet for at least 10 minutes before drying with a cloth. Gross filth and heavy soil must be removed with a cleaning solution. Discard solution when it becomes dirty and replace with fresh solution. Do not mix with OTHER CLEANERS.

DECONTAMINATION OF CRITICAL OR SEMI-CRITICAL DEVICES
STERILIZATION/HIGH LEVEL DISINFECTION: This product is not to be used as a disinfectant on any surface or instrument that (1) is introduced directly into the human body in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes 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 before sterilization or high level disinfection.

***READY TO USE THYMO-CIDE KILLS HIV ON PRE-CLEANED ENVIRONMENT**
PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in all settings in which there is a risk of soiling of inanimate surfaces/objects with blood or body fluids, and in which the soiled surfaces/objects can be associated with the potential for transmission of HIV virus type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING SURFACES PREVIOUSLY SOILED WITH BLOOD AND BODY FLUIDS WHICH MAY CONTAIN HIV-1(AIDS virus). PERSONS cleaning these surfaces should wear disposable rubber or latex gloves, gowns, face masks, or eye coverings as appropriate. **CLEANING PROCEDURE:** The solution should be applied to the surfaces and objects before disinfection. Remove visible soil/clean with solution, and disinfect surface with a second application of the solution. **DISPOSAL OF INFECTIOUS MATERIAL:** Blood and other body fluids should be disposed of according to Federal State and local regulations for infectious waste disposal.