



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

APR 30 2010

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC SUBSTANCE

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

Subject: **Thymo-Cide**
EPA Registration No. 34810-18
Application Date: April 7, 2010
Receipt Date: April 8, 2010

Dear Ms. Auer:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 2007-4 and PR Notice 98-10.

Proposed Notification:

- Updating Container Disposal statement
- Addition of marketing language
- Change of hard water efficacy claim for tuberculocidal activity from 400 ppm to 200 ppm

General Comment:

Based on a review of the submitted materials, your notification for updating the Container Disposal statements, adding marketing language and changing the hard water efficacy claim is acceptable and a part of the records on file.

Should you have any questions concerning this letter, please contact Heather Garvie at (703) 308-0034 or by email address at garvie.heather@epa.gov.

Sincerely,

Jacqueline McFarlane
(Acting) Product Manager (34)
Regulatory Management Branch
Antimicrobials Division (7510P)



Please read instructions on reverse before completing form.

Form Approved OMB (NO) 2070-0060

 United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 34810-18	2. EPA Product Manager Jacqueline McFarlane	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Thymo-Cide	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Wexford Labs, Inc. 325 Leffingwell Avenue Kirkwood, MO 63122 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Changing the hard water efficacy claim for tuberculocidal activity from 400ppm to 200ppm, updating storage and stability instructions, and adding optional marketing language. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 4.50 lbs No. per container 6	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
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** Certification must be submitted*

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 10.5" H X 4.5" W	5. Location of Label Directions <input type="checkbox"/> On the bottle
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper, glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Mary Anne Auer	Title CEO	Telephone No. (Include Area Code) 314-966-4134
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<p style="text-align: center;">Certification</p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>	6. Date Application Received (Stamped)
2. Signature 	3. Title CEO
4. Typed Name Mary Anne Auer	5. Date 4/6/2010

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WexfordLabs

The Disinfectant Solution

3/5

April 7, 2010

Ms. Jacqueline McFarlane
(Acting) Product Manager (34)
Regulatory Management Branch II
United States Environmental Protection Agency
Antimicrobial Division (7510P)
2777 Crystal Drive
Potomac Yard 1
Arlington, VA 22202

Re: 34810-18 Thymo-Cide Notification

Dear Ms. McFarlane:

I have enclosed the following:

- Form 8570-1 Notification for Thymo-Cide (EPA # 34810-18)
 - Updating Storage and Stability instructions
 - Adding optional marketing language (one-step disinfectant)
 - Changing hard water efficacy claim for tuberculocidal activity from 400ppm to 200ppm
- Three copies of our Thymo-Cide (EPA # 34810-18) updated label

We appreciate your assistance with this process.

Sincerely,
WEXFORD LABS, INC.



Mary Anne Auer
CEO

Enclosures

NOTIFICATION
Date Reviewed: 7/30/10
Reviewed By: [Signature]

[Thymo-Cide]
[CONCENTRATED GERMICIDAL DETERGENT]
[ONE-STEP DISINFECTANT]
CLEANS - DISINFECTS - DEODORIZES
Germicidal, Pseudomonacidal, Tuberculocidal, Fungicidal,
and *Virucidal in soft water or hard water with 5% Serum, on
inanimate surfaces.

Active Ingredients:

Thymol:13%
Inert Ingredients:87%
Total:100%

KEEP OUT OF REACH OF CHILDREN
DANGER

See side panel for additional precautionary statements

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

EPA Reg. No. 34810-18

EPA Est. No. [Insert Est. No. here]

FOR INDUSTRIAL AND INSTITUTIONAL USE
Contents: One Half Gallon (64 Fluid Ounces) or 1.8925 Liters

GERMICIDAL QUALIFICATIONS: (A.O.A.C. Use Dilution Confirmation) in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum at.....1:256
(A.O.A.C. Ps. aeruginosa, S. aureus, S. choleraesuis; including S. aureus [MRSA] [TNSR] [GRM] and [PR] and S. Epidermidis [MRSE])
TUBERCULOCIDAL ACTIVITY TEST: (A.O.A.C. M. tuberculosis) in the presence of 200 ppm hardness as Calcium Carbonate and 5% serum at (20° C for 10 minutes)1:256
FUNGICIDAL TEST: (A.O.A.C. T. mentagrophytes) in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum at.....1:256
VIRUCIDAL ACTIVITY TEST: (*Influenza A1/Hong Kong, Herpes simplex Type 2 and Vaccinia virus, in the presence of 400 ppm hardness and 5% serum, and HIV-1 [AIDS virus] in the presence of 400 ppm hardness as Calcium Carbonate and 10% serum on inanimate surfaces, at.....1:256

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS. DANGER. Corrosive. Causes irreversible eye damage. Harmful if absorbed through the skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a Poison Control Center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Call a Poison Control Center or doctor immediately for treatment advice.

IF SWALLOWED: Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the Poison Control Center or doctor. Call a Poison Control Center or doctor immediately for treatment advice. In case of emergency call Chemtrec at 800-424-9300. Have the product container or label with you when calling a Poison Control Center or doctor.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed. (Have the product container or label with you when calling a poison control center or doctor or going for treatment.)

Made in U.S.A.

[Thymo-Cide]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling **Do not mix with other cleaners.** For all disinfection of hard, nonporous surfaces in hospitals, health care facilities, schools, and nursing homes, such as floors, walls, bathroom fixtures, shower room stalls, use THYMO-CIDE at 1/2 ounce per gallon of water. THYMO-CIDE use-dilution may be applied with a cloth, mop or brush on surfaces such as stainless steel, chrome, glass, vinyl, ceramic, and terrazzo. Wet all surfaces thoroughly for at least 10 minutes. ** Gross filth and heavy soil must be removed before applying cleaning solution. When used for mopping or from an open pail solutions should be changed at least daily or more often if the solution becomes diluted or soiled.

DECONTAMINATION OF CRITICAL OR SEMI-CRITICAL DEVICES PRIOR TO TERMINAL STERILIZATIONS/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 normal 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.

***THYMO-CIDE KILLS HIV-1 (AIDS VIRUS) AND HBV (HEPATITIS B VIRUS) AND HCV (HEPATITIS C VIRUS) ON PRECLEANED, ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS** in health care settings or other 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: THYMO-CIDE 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 THYMO-CIDE solution, and disinfect surface with a second application of the THYMO-CIDE solution. For large spills the contaminated area should be flooded with the THYMO-CIDE solution before cleaning, then decontaminated with fresh THYMO-CIDE 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.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep upright with cap tightly closed. Store in original container in areas inaccessible to children.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill or by incineration. Do not burn unless allowed by state and local ordinances.