

34810-18

06/22/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 22 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

Subject: Thymo-Cide
EPA Reg. No. 34810-18
Application Date: May 23, 2011
Application Receipt: May 26, 2011

Dear Ms. Auer:

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

Proposed Amendment:

Wexford Labs, Inc. is making the following revisions to the label for EPA Reg. No. 34810-18:

- 1.) revised precautionary statements to adequately address EPA toxicity category III, the following statement has been added: Do not get...on skin...wear...protective clothing and protective gloves(rubber or chemical resistant) when handling;
- 2.) addition of Pandemic H1N1 claim;
- 3.) deletion of uncommon abbreviations for antibiotic resistant organisms: TNSR, GMR and PR;
- 4.) under tuberculocidal activity, M. tuberculosis has been replaced with Mycobacterium bovis.

General Comments:

Submit three (3) copies of your final printed labels before distributing or selling the product bearing the revised labeling. An EPA stamped "accepted" label is enclosed for your records.

If you have questions concerning this letter, then please contact me at 703-308-6416 or by email at campbell-mcfarlane.jacqueline@epa.gov or Killian Swift at 703-308-6346 or by email at swift.killian@epa.gov. When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,

Jacqueline Campbell-McFarlane
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: EPA stamped "accepted" label.

[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.

[Whirlpool Pedicure Spa One-Step Disinfectant]

[Concentrated One-Step Germicidal Detergent]

[For use in Whirlpool baths, Foot Spas, Beauty Salons, Barber shops and
Hospitals]

Active Ingredients:

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

KEEP OUT OF REACH OF CHILDREN DANGER

See side panel for additional precautionary statements

[Thymo-Cide] [Is to clean and disinfect washable hard nonporous surfaces of:
whirlpool baths, foot spas, salon/barber tools and instruments: combs, brushes,
and manicure instruments.]

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, 10 minute contact time at .. 1:256
(A.O.A.C. Ps. aeruginosa, S. aureus, S. enterica; including S. aureus [MRSA] and S.
Epidermidis [MRSE])

TUBERCULOCIDAL ACTIVITY TEST: (A.O.A.C. M. bovis BCG) 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, 10 minute contact time at 1:256

VIRUCIDAL ACTIVITY TEST*: Influenza A1/Hong Kong, Pandemic 2009 H1N1 Influenza A
Virus (formerly called Swine Flu), Herpes simplex Type 2 and Vaccinia virus, in the
presence of 400 ppm hardness and 5% serum, 10 minute contact time at 1:256
HIV-1 [AIDS virus] in the presence of 400 ppm hardness as Calcium Carbonate and 10%
serum, one minute contact time 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, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety
glasses) protective clothing and protective gloves (rubber or chemical
resistant) when handling. Wash hands before eating, drinking, chewing gum, using
tobacco, or using the toilet. Remove contaminated clothing and wash clothing before
reuse.

FIRST AID

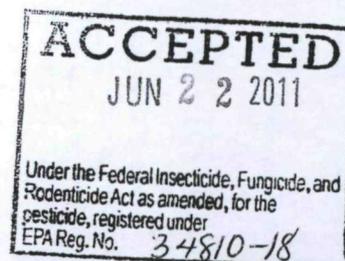
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes.
Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
Call a Poison Control Center or doctor for treatment advice.

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.



Note to reviewer: Language in [] is optional or interchangeable

[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 [this product] at 1/2 ounce per gallon of water. [This product's] use solution may be applied with a cloth, mop or brush, or by immersing equipment to be disinfected. Wet all surfaces thoroughly. Let solution remain on surface for a minimum of 10 minutes. Rinse or allow to air dry. [This product's] use solution may be used on surfaces such as stainless steel, chrome, glass, vinyl, glazed ceramic, and terrazzo. Gross filth and heavy soil must be removed before applying cleaning solution. When used for mopping or from an open pail, solution should be changed at least daily or more often if the solution becomes diluted or soiled.

[AREAS OF USE:]

[Hospitals]	[Schools]
[Health Care Facilities]	[Bathrooms]
[Medical Offices]	[Whirlpool (baths) (units)]
[Dental offices]	[Foot spas]
[Day care centers]	[Salons (Beauty)]
[Nurseries]	[Whirlpool pedicure spa]
[Nursing homes]	[Institutions]
[Barber Shops]	[Institutional facilities]

[TYPES OF SURFACES:]

[On washable hard, nonporous surfaces of:]

[Bathroom fixtures]	[Floors]
[Stainless Steel]	[Walls]
[Chrome]	[Glass]
[Vinyl]	[Glazed Ceramic]
[Terrazzo]	

[SALON/BARBER INSTRUMENTS AND TOOLS DISINFECTION BACTERICIDE / VIRUCIDE/ FUNGICIDE DIRECTIONS:

Mix 1/2 oz. (15 ml) of [this product] per gallon of water (0.125 oz (3.75 mL) of this product per quart of water) to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Fresh solution must be prepared daily or more often if solution becomes diluted or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.]

[WHIRLPOOL FOOT SPA DISINFECTION: After using whirlpool foot spa, drain the water. Use 1/2 oz. of [this product] per gallon of water to cover intake valve. Start pump to circulate the solution. Swab exposed surfaces including unit sides, chairs, and any related equipment thoroughly with cloth, sponge, or brush and allow treated surfaces and solution to stand for 10 minutes. After unit has been thoroughly disinfected, rinse all disinfected surfaces with fresh water.]

[DISINFECTION OF [WHIRLPOOL (BATH(S) (UNITS))]:

After using the [whirlpool (bath) (unit)], drain and refill with fresh water to (just cover the intake valve) (cover the highest jet) (2 inches above the highest jet). Add 1/2 ounce of [this product] for each gallon of fresh water added. Start the pump to circulate the solution. Wash down [the (deck) (seat of chair) (any related equipment)] any uncovered surfaces on the (bath) (unit) with a clean swab, brush or sponge with the solution. Treated surfaces must remain wet for 10 minutes. After the (bath) (unit) has been thoroughly disinfected, drain and rinse surfaces with fresh water. Wipe dry with a clean sponge or cloth or allow to air dry. Repeat for heavily soiled units.]

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.

***[this product] KILLS HUMAN IMMUNODIFICIENCY VIRUS TYPE1 (HIV) 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 and eye coverings as appropriate when performing manual cleaning of these surfaces. **Contact Time:** Leave surfaces wet for 1 minutes with a solution of 1/2 oz per gallon of water. This contact time will not control other common types of viruses and bacteria listed on the label.

CLEANING PROCEDURE: [This product] use 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 [this product's] solution, and disinfect surface with a second application of the [this product's] solution. For large spills the contaminated area should be flooded with the [this product's] solution before cleaning, then decontaminated with fresh [this product's] solution.

DISPOSAL OF INFECTIOUS MATERIAL: Blood , body fluids, cleaning materials and clothing must 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.

