



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

October 10, 2017

Mary Jo Thierry  
Chief Operating Officer  
Wexford Labs, Inc.  
325 Leffingwell Avenue  
Kirkwood, MO 63122

Subject: Label Amendment – Additional marketing language, use sites, revised directions  
Product Name: Ready To Use Thymo-Cide  
EPA Registration Number: 34810-25  
Application Date: May 18, 2017  
Decision Number: 530664

Dear Ms. Thierry:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Tom Luminello by phone at (703) 308-8075 number, or via email at [luminello.tom@epa.gov](mailto:luminello.tom@epa.gov).

Sincerely,

A handwritten signature in red ink that reads "Jacqueline Hardy". The signature is written in a cursive style and is enclosed within a faint, light-colored rectangular border.

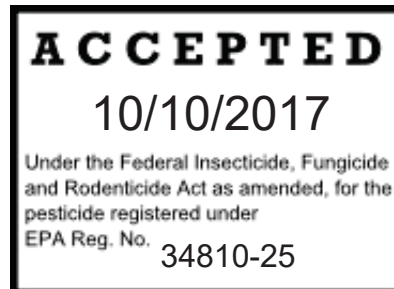
Jacqueline Hardy  
Product Manager 34  
Regulatory Management Branch 2  
Antimicrobials Division (7510P)

Enclosure      Stamped Label

{All text in brackets [xxx] is optional & may or may not be included on a final label.}  
{All text in braces {xxx} is administrative & will not appear on a final label.}

[READY TO USE THYMO-CIDE]  
[Germicide] [Tuberculocide] [Fungicide] [Virucide\*]

ACTIVE INGREDIENT:  
Thymol .....0.051%  
INERT INGREDIENTS: .....99.949%  
[Includes detergents, perfume and water]  
TOTAL: ..... 100.000%



[CAUTION]  
KEEP OUT OF REACH OF CHILDREN

[FIRST AID

**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 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 with soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.]

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

EPA REG. NO. 34810-25 • EPA EST. NO. 34810-MO-1  
Net Contents: \_\_\_\_ [oz] [gal] [ml]  
[Batch Code : \_\_\_\_\_ for non-refillable containers]

***Efficacy Claims***

**At a contact time of 10 minutes [and in the presence of 5% blood serum] is effective against**

[Kills over 99.9% of bacteria, specifically]

[**GERMICIDAL:**] [**ACTIVITY:**] [(AOAC Use Dilution Confirmation in the presence of 5% serum at 20° C for 10 minutes.)]

[Pseudomonas aeruginosa [Ps. Aeruginosa] (ATCC 15442)]

[Staphylococcus aureus [S. aureus] (ATCC 6538)]

[Salmonella enterica [S. enterica] (ATCC 10708)]

[**BROAD SPECTRUM DATA:**] [(AOAC Use Dilution Confirmation in the presence of 5% serum at 20° C for 10 minutes.)]

[Methicillin resistant Staphylococcus aureus (MRSA)\*\*]

[Methicillin resistant Staphylococcus epidermidis (MRSE)\*\* ]

[Tetracycline Novobiocin Streptomycin resistant Staphylococcus aureus (TNSR) (ATCC 27659)]

[Gentamicin Methicillin resistant Staphylococcus aureus (GMR) (ATCC 33592)]

[Penicillin resistant Staphylococcus aureus (PR) (ATCC 11631)]

[Vancomycin Resistant Enterococcus faecalis (VRE) (ATCC 51299)]

[\*\* Clinical Isolates]

**[TUBERCULOCIDAL:] [ACTIVITY:]** [Tuberculocidal in the presence of 5% serum at 20° C for 10 minutes. AOAC Mycobacterium bovis [M. tuberculosis] [TB]]

[Kills over 99.9% of molds, specifically]

**[FUNGICIDAL:] [ACTIVITY:]** [Trichophyton interdigitale (ATCC 9533) in the presence of 5% serum at 20° C for 10 minutes.]

[Kills over 99.9% of viruses, specifically]

**[VIRUCIDAL:] [ACTIVITY:]**

[\*Influenza A3 Virus (Hong Kong)]

[Herpes Simplex Virus Type 2]

[Vaccinia Virus]

[Human Rotavirus]

[Respiratory Syncytial Virus (ATCC VR 26) in the presence of 5% serum at 20° C for 10 minutes.]

[Human immunodeficiency virus Type 1 (HIV-1) (AIDS Virus) in the presence of 10% serum on hard, non-porous surfaces at 20° C for 1 minute.]

[This product has demonstrated effectiveness against influenza A3 virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).]

**OPTIONAL MARKETING CLAIMS:**

- Bactericidal
- Bactericide
- Botanical
- Botanical Cleaner
- Botanically Derived Active Ingredient
- Broad spectrum disinfectant cleaner
- Cleans
- Decontaminant
- Deodorizes
- Disinfectant Cleaner
- Disinfects
- Fungicidal
- Germicidal
- Hospital Disinfectant
- Instrument PreSoak
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)
- One-Step
- Pseudomonacidal
- Serum Effective One-Step Germicidal Detergent
- Tuberculocidal
- Virucidal\*
- With 5% serum

***Fragrance Descriptors:***

- [Herbal Scent]
- [Citrus Scent]
- [Cranberry] [Scent]
- [Rose] [Scent]

## DIRECTIONS FOR USE

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

**CLEANING AND DISINFECTING DIRECTIONS:** Gross filth and heavy soil must be removed before applying cleaning solution. Apply to surfaces by cloth, sponge, brush, coarse spray or by immersing equipment using normal cleaning methods. All hard surfaces must be wet thoroughly, and remain wet for at least 10 minutes and allowed to air dry. Thoroughly rinse all wetted and cleaned food contact surfaces with potable water. As the solution becomes dirty discard and replace with fresh solution. This is a complete product. **DO NOT MIX WITH OTHER CHEMICALS.**

[This product] is a [germicidal detergent] [with broad spectrum kill of gram positive and gram negative microorganisms] formulated to clean, disinfect and deodorize in a simple one-step process. [It is an excellent [one-step] cleaner [disinfectant] for working surfaces, including stainless steel, chrome, glass and vinyl]. [It effectively controls odors produced by odor causing bacteria and leaves a fresh citrus scent.] [Passes AOAC Use Dilution Confirmation in the presence of 5% organic soil load at 20° C for 10 minutes.]

## USAGE CLAIMS

[This product] is [suitable] [intended] [for] [use] [on] [in] all disinfection of hard, non-porous surfaces ([floors] [walls] [tables] [etc.]) in

[Ambulances]	[Nurseries]
[Athletic facilities]	[Nursing Homes]
[Cafeterias]	[Operating Rooms]
[Coils and drain pans* of HVAC & R equipment]	[Oral Healthcare Facilities]
[[Dental] and [Medical] Offices]	[Oral Surgery Centers]
[Dental Labs]	[by Police and EMS]
[Dental Operatories]	[Prisons]
[Dental Schools]	[Public areas]
[Emergency Areas]	[Public restrooms]
[Healthcare Facilities] [including]	[Residential]
[Hospitals]	[Restaurants]
[Hotels and motels]	[Schools]
[Institutional kitchens]	[Shower and bath areas]
[Intensive Care]	[Zoos]
[Military installations]	
[as well as other areas/facilities concerned with the hazards of cross contamination]	

\*Drain pans must be pre-cleaned and dry before applying this product

[TYPES OF SURFACES/USE SITES:] [Graphic –depicting surface]

[Use for one-step cleaning, disinfecting and deodorizing of devices and surfaces potentially contaminated with microorganisms and other items made of]

[When used as directed, [this product] effectively cleans and disinfects hard, non-porous environmental surfaces such as]

[ambulance patient care surfaces]	[infant care equipment]	[play mats]
[anesthesia equipment surfaces]	[keyboards]	[Plexiglas®]
[baby/infant care surfaces]	[laboratory equipment/surfaces]	[radiology equipment surfaces]
[backboards]	[lights]	[rubber]
[bathing units]	[light lens covers]	[refrigerators (exterior surface)]
[bathrooms]	[linoleum]	[respirators]
[bed railings]	[lumens]	[respiratory care equipment surfaces]
[blood pressure devices]	[medical equipment surfaces/devices]	[shower floors/walls]
[cabinets]	[metal]	[sinks]
[chairs]	[microscopes]	[skin care equipment/surfaces]
[changing tables]	[MRI equipment surfaces]	[soaking containers]
[chrome]	[neonatal/nursery surfaces]	[stainless steel]
[computer surfaces]	[non-porous vinyl]	[stalls]
[countertops]	[obstetrical equipment surfaces]	[surgical equipment surfaces]
[CT equipment/surfaces]	[operating room lights/tables]	[surgical microscopes]
[curing lights]	[ophthalmic equipment surfaces/devices]	[tables]
[dental equipment surfaces/devices]	[optical wear (excluding contact lenses)]	[telephones]
[doorknobs]	[oxygen hoods]	[toilets (rims, seats and exterior surfaces)]
[floors]	[patient bed surfaces]	[toys]
[garbage cans]	[patient stretchers]	[transportation equipment surfaces]
[glass]	[patient transport surfaces]	[trays]
[glazed porcelain]	[physical therapy equipment]	[walls]
[glazed tile]	[plastics]	[washable painted or varnished surfaces]
[highchairs]	[play-care equipment]	[work stations]
		[x-ray equipment/surfaces]
[other areas/facilities concerned with the hazards of cross contamination]		

**ODOR CONTROL:** It effectively controls odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors and leaving a pleasant fragrance. Follow “**CLEANING AND DISINFECTING DIRECTIONS**”.

**TO CLEAN, DEODORIZE AND REMOVE DEBRIS FROM CARPETS AND FABRICS**

**To Spot Clean:** Blot or scrub area to be treated with [Brand name] Disinfectant Solution to remove soiling. Wipe dry with clean cloth or towel.

**To Deep Clean Carpets, Upholstery and Fabrics:** Vacuum to remove loose dirt and soiling. Thoroughly moisten with product using coarse tip pressure sprayer and rake or brush into nap. Clean treated areas using clean water extraction method, such as portable or truck-mounted carpet cleaning machine or upholstery cleaning machine. Allow to dry thoroughly prior to using. Always spot test in inconspicuous area prior to application for compatibility.

### **Deodorizing and Cleaning of Carpet/Fabrics**

To Deodorize and Clean Carpets, Fabrics, and other Materials: [*Brand name*] can be used on most fabrics that can be cleaned with water-based cleaners. Not for use on wool, silk, or suede. Always test for color fastness and material compatibility in an inconspicuous area prior to use. Apply by sprayer, to ensure even coverage and allow for 10 minute contact time. Do not rinse, use hot water extraction wand to remove product from treated surfaces and then dry stroke carpet to remove excess moisture. Carpet can be air dried or fans may be used if carpet needs to dry more quickly.

***Where medical devices are listed as applicable sites, the following will be included as required by PR 94-4***

**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.

***The following special instructions must be included on the label if the product is used as a hospital-grade disinfectant rather than retail/household***

**\*[This product] 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 hard, non-porous 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 virus).

**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 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 must be flooded with the solution before cleaning, then decontaminated with fresh solution. **DISPOSAL OF INFECTIOUS MATERIAL:** Blood and other body fluids must be autoclaved and disposed of according to Federal State and local regulations for infectious waste disposal.

**Storage and Disposal:**

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

**Pesticide Storage:**

Store at room temperature. Do not leave containers of this product open during storage.

Store in original container in areas inaccessible to children and persons unfamiliar with its use.

**Pesticide Disposal:**

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**Container Handling:**

{For non-refillable container:} Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap container and put in trash or offer for recycling if available.

{For refillable container:} Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, triple rinse container (or equivalent) promptly after emptying. Offer for recycling, if available.

***Revised: 10/06/2017***