



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 4, 2016

Ms. Mary Jo Thierry
Wexford Labs, Inc
325 Leffingwell Avenue
Kirkwood, MO 63122

Subject: Notification per PRN 98-10 – Revise HIV-1 Directions
Product Name: Ready-To- Use Thymo-Cide
EPA Registration Number: 34810-25
Application Date: 10/5/2016
Decision Number: 524027

Dear Ms. Thierry:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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.

If you have any questions, you may contact Farzana Olla at 703-347-0190 or via email at olla.farzana@epa.gov.

Sincerely,

A handwritten signature in red ink that reads "Jacqueline Hardy".

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

{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

[ONE-STEP] GERMICIDAL DETERGENT
[SERUM EFFECTIVE ONE-STEP GERMICIDAL DETERGENT]
CLEANS • DISINFECTS • DEODORIZES

GERMICIDE [GERMICIDAL]
[PSEUDOMONACIDAL]
[BACTERICIDAL] [BACTERICIDE]
TUBERCULOCIDE [TUBERCULOCIDAL]
FUNGICIDE [FUNGICIDAL]
VIRUCIDE* [VIRUCIDAL*] [with 5% Serum]

NOTIFICATION

34810-25
The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

11/4/2016

ACTIVE INGREDIENT:

Thymol0.051%
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]

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 (GRM) (ATCC 33592), Penicillin resistant Staphylococcus (PR) (ATCC 11631), 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]

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

VIRUCIDAL ACTIVITY: *Influenza A3 (Hong Kong), Herpes Simplex Type 2 (VR 734), Vaccinia Virus, Human Rotavirus, and Respiratory Syncytial Virus (VR 26) in the presence of 5% serum at 20° C for 10 minutes. Human immunodeficiency virus Type 1 (HIV-1) (AIDS) 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).

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.**

Ready To Use Thymo-Cide 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.]

Use Ready To Use Thymo-Cide for all disinfection of hard, non-porous surfaces (floors, walls, tables, etc.) in Healthcare Facilities including [Operating Rooms], [Intensive Care], [Nurseries], [Emergency Areas], [Dental Operatories], [Dental and Medical Offices], [Oral Healthcare Facilities], [Oral Surgery Centers], [Dental Schools], [Schools], [Hospitals], [Nursing Homes], [Prisons], [Dental Labs], [by Police and EMS], [Residential], [Restoration,, decontamination and remediation sites (Fire, water, sewage, trauma scene decontamination and remediation)] as well as other areas/facilities concerned with the hazards of cross contamination.

[Use for one-step cleaning, disinfecting and deodorizing of devices and surfaces potentially contaminated with microorganisms and other items made of stainless steel, chrome, glass, non-

porous vinyl, glazed porcelain, metal, plastics, Plexiglas®, glazed tile, washable painted or varnished surfaces, linoleum, and rubber.]

[When used as directed, Ready To Use Thymo-Cide effectively cleans and disinfects hard, non-porous environmental surfaces such as: ambulance patient care surfaces, anesthesia equipment surfaces, baby/infant care surfaces, backboards, bathing units, bathrooms, bed railings, blood pressure devices, cabinets, chairs, changing tables, computer surfaces, countertops, CT equipment/surfaces, curing lights, dental equipment surfaces/devices, doorknobs, floors, garbage cans, highchairs, infant care equipment, keyboards, laboratory equipment/surfaces, lights, light lens covers, lumens, medical equipment surfaces/devices, microscopes, MRI equipment surfaces, neonatal/nursery surfaces, obstetrical equipment surfaces, operating room lights/tables, ophthalmic equipment surfaces/devices, optical wear (excluding contact lenses), oxygen hoods, patient bed surfaces, patient stretchers, patient transport surfaces, physical therapy equipment, play-care equipment, play mats, radiology equipment surfaces, refrigerators (exterior surface), respirators, respiratory care equipment surfaces, sinks, soaking containers, stalls, shower floors/walls, skin care equipment/surfaces, surgical equipment surfaces, surgical microscopes, tables, telephones, toilets (rims, seats and exterior surfaces), toys, transportation equipment surfaces, trays, walls, work stations, x-ray equipment/surfaces, and other areas/facilities concerned with the hazards of cross contamination.]

[Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)]

[Hospital Disinfectant]

[Instrument PreSoak]

[Disinfectant Cleaner]

[Decontaminant]

[Herbal Scent]

[Citrus Scent]

[Botanical Cleaner]

[Botanical]

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.

Bold, italicized text is information for the reader and is not part of the label. [Bracketed information is optional text.] **Highlighted text is new.** Strike-through (text) means removed.

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 should be included on the label if the product is used as a hospital-grade disinfectant rather than retail/household

***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 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).

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 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.