



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 22, 2015

Bob MacDonald
Scientific & Regulatory Consultants, Inc.
Agent for Laboratoire M2
201 W. Van Buren Street
Columbia City, IN 46725

Subject: PRIA Label Amendment – Adding Mycobacterium bovis claim
Product Name: Thymox® Disinfectant Spray
EPA Registration Number: 87742-1
Application Date: March 6, 2015
Decision Number: 501791

Dear Mr. MacDonald:

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. The next label printing of this product must use this labeling unless subsequent changes have been approved. 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.

Page 2 of 2
EPA Reg. No. 87742-1
Decision No. 501791

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 Stacey Grigsby by phone at number, or via email at grigsby.stacey@epa.gov .

Sincerely,

A handwritten signature in cursive script that reads "Stacey Grigsby".

Stacey Grigsby
Risk Manager
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: Accepted Stamped Label

PRODUCT : Thymox® Disinfectant Spray
EPA Reg. No. : 87742-1

{The efficacy of} [Thymox® Disinfectant Spray] [this product] [was shown in the presence of 5% organic serum] [.] [against:] [.] [its effective against] [kills][eliminates]:]

[99.99% of] [Bacteria][specifically]
 [Staphylococcus aureus] [Salmonella enterica (choleraesuis)] [Pseudomonas aeruginosa] [Escherichia] [E.] [coli] [Escherichia] [E.] [coli] [O157:H7] [Methicillin-Resistant] [Staphylococcus aureus] [MRSA] [Vancomycin-Resistant] [Enterococcus faecalis] [VRE] [Listeria monocytogenes] [Listeria] [Klebsiella pneumoniae] [K. pneumoniae] [– NDM-1 positive] [Streptococcus suis] [after a contact time of two minutes].

[99.99% of] [Fungi and molds] [specifically]
 [Trichophyton mentagrophytes [Athlete's Foot Fungus] [Candida albicans] [after a contact time of three minutes].

[99.9% of] [Viruses*] [specifically]
 [*Human Coronavirus] [*HIV-1*] [AIDS virus]] [*Swine Influenza A] [*Pandemic Human Influenza A] [(H1N1)] [after a contact time of one minute].

{The following claim may appear on the label:}
 {Respiratory illnesses attributable to Severe Acute Respiratory Syndrome ("SARS") are caused by a Coronavirus. Thymox® Disinfectant Spray is a broad-spectrum hard surface disinfectant that has been shown to be effective against other similar viruses.}

[PANDEMIC 2009 H1N1 INFLUENZA A VIRUS]

{One of the following claims may appear on the label}
 {This product [Thymox® Disinfectant Spray] has demonstrated effectiveness against Swine Influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).}
 {Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. This product [Thymox® Disinfectant Spray] is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza A virus tested and listed on the label) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).}
 {This product [Thymox® Disinfectant Spray] has demonstrated effectiveness against Influenza A virus tested and listed on the label) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).}
 [Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).]
 [Kills Pandemic 2009 H1N1 Influenza A virus.]

{The following claims and instructions may appear on the label:}

***KILLS HIV-1 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/body fluids and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of HIV-1 (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.
PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable [protective] [latex] gloves, gown, masks and eye protection.
CLEANING PROCEDURES: Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of [Thymox® Disinfectant Spray][this product].
CONTACT TIME: Allow surface to remain wet for 1 minute. A 2 minute contact time is needed for bacteria and a 3 minute contact time for fungi.
DISPOSAL OF INFECTIOUS MATERIAL: Blood/body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

{Master Label}
Thymox® Disinfectant Spray {on front label}

[For [Household][.] [Hospitals][.] [Institutional]] [and] [Industrial] Use] [One-step Hospital Disinfectant Cleaner]

[Thymox® Disinfectant Spray][our formula] [This product] [is a patented technology][formula] [and] [kills] [destroys] [eliminates] [the following] [household] [germs][microbes] [microorganisms] [commonly found on household surfaces] [.]

[Thymox® Disinfectant Spray][This product is] [a] [one-step] [hospital] [disinfectant-cleaner] [Bactericidal][.] [and] [Tubercuicidal] [Mycobactericidal] [.] [and] [Fungicidal][according to the AOAC Germicidal Spray Method][and] [Virucidal*][according to the ASTM Standard Test Method for Efficacy of Virucidal Agents].]

ACTIVE INGREDIENT:

Thymol (present as a component of thyme oil)..... 0.23%

OTHER INGREDIENTS:..... 99.77%

Total..... 100.00%

{on front label}

Keep Out Of Reach Of Children {on front label}

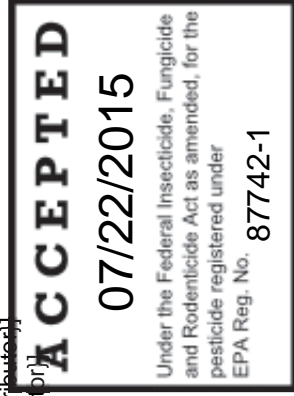
[CAUTION {on front label}]

Manufactured by
 Laboratoire M2
 4005-A, Rue de la Garlock, Sherbrooke
 Québec, J1L 1W9 CANADA

EPA Reg. No. 87742-1 EPA Est. No. 87742-CAN-001

{The contents, in US measurement, will appear on the front label}
 Net content [XXX] fl oz [xxx mL]

Made in {country}
 Manufactured for {name of distributor}
 {address of distributor}
 [{phone number of distributor}]
 [{website of distributor}]



{All text in brackets [] is optional and may or may not appear on the printed label} {All text in braces {} is meant to facilitate the reviewer's comprehension of the document, and will not appear on the printed label} V.1.4

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Heavily soiled [or greasy] [area] [surfaces] require a pre-cleaning.

{The following use directions for cleaning may appear on the label:}

TO CLEAN [and] [DEODORIZE]: [Apply] [Spray] the product [on] [to] [the soiled] [area] [surface] [and] [wipe clean]. [To] [dislodge] [remove] [eliminate] [stubborn] [tough] [heavy] [stains] [dirt] [soil] [allow] [let] [leave] [product] [to] [stand] [act] [for] [1] [2] [3] [4] [5] [minutes] [a few minutes] [and] [wipe clean].]

TO DISINFECT: [Spray to] [thoroughly] [completely] [wet] the surface [to be disinfected] with [the] [product] [spray] [Thymox® Disinfectant Spray] [(spot test to check compatibility with the surface)]. [Let] [Allow to] [Leave for] [stand] [3 minutes to eliminate fungi] [.] [2 minutes to eliminate bacteria] [.] [3 minutes to eliminate M. bovis BCG [TB]] [and] [1 minute to eliminate viruses*] [.] [Allow to air dry.] [If desired, wipe dry.]
{One of the following statements will appear on the label:}

- 1- No rinsing [or wiping] required on non-food contact surfaces except on direct food contact surfaces which require a potable water rinse after treatment.
 - 2- On food contact surfaces, a rinse with potable water is required.
- Food products and packaging materials must be removed or carefully protected prior to using this product.

{The following use directions for sanitization may appear on the label:}

TO SANITIZE: [Spray to] [thoroughly] [completely] [wet the surface to be sanitized with] [the] [product] [spray] [Thymox® Disinfectant Spray]. [Let] [Allow to] [Leave for] [stand] [30 seconds] [.] [No rinsing required on non-food contact surfaces.] On food contact surfaces, a rinse with potable water is required. Food products and packaging materials must be removed or carefully protected prior to using this product. This product is effective as a Non-Food Contact Sanitizer on hard non-porous surfaces against Enterobacter aerogenes and Staphylococcus aureus in 30 seconds.

{The following use directions for Farms Premises and Veterinary use may appear on the label:}

[FARM PREMISES AND VETERINARY USE:

1. Remove all animals and feed from premises, vehicles, and enclosures.
2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate all surfaces with the disinfecting solution for a period of [3 minutes for fungi] [.] [2 minutes for bacteria] [and/or] [1 minute for viruses*]
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Rinse all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with potable water before reuse.]

[You can] [Use] [Thymox® Disinfectant Spray] [this product] [in] [on the following hard non-food, non-porous surfaces:] [the kitchen] [the bathroom] [your house] [public areas] [the office] [Medical] [Dental] [Offices] [Waiting room] [Health Care Facilities] [Clinics] [Hospitals] [Nursing Homes] [Day Care Center] [Nurseries] [Ambulances] [Institutional Kitchens] [Catererias] [Stores] [Restaurants] [Food Processing Plants]	[Public Restrooms] [Taxis] [Hotels and Motels] [Institutional facilities] [Correctional facilities] [Military Installations] [Schools] [Church] [Dormitory] [Classrooms] [Colleges] [Athletic facilities] [Shower and Bath areas] [Barber Shops, Beauty and Tanning Salons] [Farms (Livestock; Dairy; Fruits and Vegetables)] [Zoos]
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[You can] [Use] [Thymox® Disinfectant Spray] [this product] [Suitable for use] [on] [any] [all] [hard, non-porous surfaces] [where] [bacterial] [virus*] [microbes] [microorganisms] [germs] [or] [strong, unpleasant] [odors] [reside] [are] [usually] present [are likely to be present] [are a concern] [.] [including] [such as] [.] [.]

[Countertops] [Stovetops] [Refrigerator exteriors] [Trash Cans] [Floors] [Children's] [School] [Toys] – rinse with potable water after application of Thymox® Disinfectant Spray] [Appliance exteriors] [Baby Furniture] [Changing tables] [Cribs] [Highchairs] [Telephones] [Garbage cans] [Door handles]	[PPE (personal protective equipment)] [Hard, non-porous surfaces of Sinks] [Bathtubs] [Vanities] [Walls] [Windows] [Mirrors] [Toilet seats] [Hard sporting equipment] [Cups] [Helmets] [Examination Tables] [Patient Chairs] [Tables] [Door]
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[The product] [it] [will not] [harm] [damage] [Use on] [hard] [Non-porous] [materials] [surfaces] [such as] [.] [.] [Metal] [Glazed Ceramic] [Glazed Porcelain] [Glazed enameled surfaces] [Glass] [Sealed Marble] [Steel] [Stainless Steel]	[Brass] [Aluminum] [Sealed Concrete] [Plastic (such as polypropylene, polystyrene, polyethylene, PVC)] [Glazed Tile] [Sealed Fiberglass]
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{The following is only for products with medical devices listed on label:}

Note: 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

{The following directions for Storage and Disposal will appear on the label according to the intended use}

{HOUSEHOLD OR RESIDENTIAL USE}

STORAGE AND DISPOSAL

Store at room temperature [20-25C][68F-77F] in a secure area inaccessible to children. Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or discard in the trash.

{NONREFILLABLE CONTAINERS FOR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL USES – ALL SIZES}

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store at room temperature [20-25C][68F-77F] in a secure area inaccessible to children.

PESTICIDE DISPOSAL: Use up product in accordance to use directions. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill empty container. Triple rinse promptly, then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

{REFILLABLE CONTAINERS FOR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL USES – ALL SIZES}

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store at room temperature [20-25C][68F-77F] in a secure area inaccessible to children.

PESTICIDE DISPOSAL: Use up product in accordance to use directions. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before refilling is the responsibility of the person disposing of the container. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat this procedure two more times. For final container disposal: offer for recycling or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or incinerate, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

[New!] [Brand New!] {up to 6 months after date of first sale}

{All text in brackets [] is optional and may or may not appear on the printed label} {All text in braces {} is meant to facilitate the reviewer's comprehension of the document, and will not appear on the printed label} V1.4

[Cleaning and Disinfecting Formula]
[Streak-free][Sparkling shine]
[Ready to Use [(RTU)]]
[A better way to clean]

[Try it on your mirrors!]
[Contains] [no Chlorine]
[Contains] [no Phosphates]
[Botanically derived active ingredient]
[Essential Oils Technology]
[Thymol, [is] a component of Thyme Oil]
[Cleaning Thyme!]
[Thyme for change!]
[Cuts Cleaning Thyme!]

{*name of actual scent in product*} [scent]
[Leaves a] [Fresh] [pleasant] [Thyme] [scent]
[Leaves a] [pleasant] [Fresh] [and] [clean] [Thyme] {*name of actual scent in product*} [aroma]
[Leaves a botanical scent]

{*These claims only if no artificial odor is actually added to the product*}
[Contains] [no fragrance]
[No [artificial] fragrance added]
[Fragrance free]

[Disinfects bacteria, fungi and viruses* in 3 minutes!]
[Disinfects bacteria in 2 minutes!] [Disinfects viruses* in 1 minute!]
[Kills TB in 3 minutes!] [Kills M. bovis BCG in 3 minutes!] [Kills mycobacteria in 3 minutes!]
[Kills Mycobacterium bovis (TB) in 3 minutes!]
[Inventor][Laboratoire M2 Logo]

[Optional Graphic – following graphic may or may not appear on label]



[Kills] [Reduces][Disinfects][Eliminates] [over] [99.99% of] [household] [bacteria] [germs] [viruses*] [in 3 minutes] [on hard, nonporous surfaces] [specifically] [including] [such as]

[Staphylococcus aureus] [S. aureus] [Staph]
[Salmonella enterica] [(choleraesuis)] [S. enterica] [Salmonella]
[Pseudomonas aeruginosa] [P. aeruginosa] [Pseudomonas]
[Escherichia coli] [E. coli]
[Escherichia coli O157:H7] [E. coli O157:H7]
[Methicillin-Resistant] [Staphylococcus [S.] aureus] [MRSA]
[Vancomycin-Resistant] [Enterococcus faecalis] [VRE]
[Listeria monocytogenes] [Listeria]
[Klebsiella pneumoniae – NDM-1 positive] [K. pneumoniae NDM-1]
[Streptococcus suis] [S. suis] [Streptococcus]
[in 2 minutes] [on hard, nonporous surfaces]

[Trichophyton mentagrophytes][Athlete's Foot Fungus][T.][Trichophyton] [mentagrophytes][ment.]]
[Candida albicans] [C. albicans] [Candida]
[in 3 minutes] [on hard, nonporous surfaces]

[*Human Coronavirus] [*Coronavirus]
[*HIV-1*] [AIDS virus]
[Swine*influenza A] [(H1N1)] [pandemic *influenza A H1N1]
[in 1 minutes] [on hard, nonporous surfaces]

[Mycobacterium bovis BCG] [M. bovis BCG][Mycobacterium bovis (TB)] [in 3 minutes] [on hard, nonporous surfaces]

[Broad-Spectrum Disinfectant] [Disinfectant]
[All purpose Cleaner]
[Kitchen Cleaner]
[Bathroom Cleaner]
[General Household Cleaner]
[Disinfecting] [Disinfectant] [Cleaner][Cleaning][Spray]
[Disinfectant Cleaner Spray]
[For everyday use]
[Tough on dirt][!]
[Heavy Duty]
[Cleaner and Disinfectant] [in a single bottle.]
[2 in 1 Household Cleaner & Disinfectant]
[One Step Cleaner & Disinfectant]
[Disinfects and cleans] [!] [at the same time]
[Deodorizes]
[Effectively][Controls][unpleasant][strong][odors]
[Deodorizer]
[Cleans, disinfects and deodorizes] [!]
[Cleans and Disinfects without bleaching]
[Non abrasive formula]
[Disinfects] [as it cleans] [while you clean]
[Disinfectant Cleaner]
[Multi-Surface Cleaner]
[Cuts grease][&][grime]!