



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 3, 2017

Robert MacDonald
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street
Columbia, City, IN 46725

Subject: PRIA Label Amendment – *Adding additional organisms against Respiratory Syncytial*
Product Name: Thymox Disinfectant Spray
EPA Registration Number: 87742-1
Application Date: May 11, 2017
Decision Number: 529470

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. 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 Stacey Grigsby by phone at 703.305.6440, or via email at grigsby.stacey@epa.gov.

Sincerely,

A handwritten signature in red ink that reads "Jacqueline Hardy". The signature is written in a cursive style and is centered on the page.

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

Enclosure: Accepted Stamped Label
8/29/17 Efficacy Review
9/20/17 Chemistry Review

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][dir][soil] [allow][let] [leave] [product] [to] [stand] [act] [for][1][2][3][4][5][minutes][a few minutes][and]& [wipe clean.] [Heavily soiled surfaces require a pre-cleaning with a non-scratch sponge.]

[TO REFILL:] [Remove sprayer. Pour in product from refill container. Replace sprayer]

{Disinfecting & Non-Food Contact Sanitizing Directions for all accepted formulas/CSFs}

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 fungal] [1.] [2 minutes to eliminate bacterial] [1.] [3 minutes to eliminate M. bovis BCG [TB]] [and] [1 minute to eliminate viruses*] [1.] [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] [1.] [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] [1.] [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.]

{Use Directions only for Basic CSF and Alternate 9 (formula acceptable for surfaces that when dry may directly contact food)}

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 fungal] [1.] [2 minutes to eliminate bacterial] [1.] [3 minutes to eliminate M. bovis BCG [TB]] [and] [1 minute to eliminate viruses*] [1.] [Allow to air dry.] [if desired, wipe dry.]

[On food contact surfaces, no rinse is required][No rinse required, even on food contact surfaces]

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] [1.] [No rinsing 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.]

BARBER/BEAUTY SALON INSTRUMENTS AND TOOLS: Immerse pre-cleaned barber/beauty saloinstruments and tools (such as combs, brushes, razors, scissors, blades, and manicure instruments) in ready to use solution for 3 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. A fresh solution must be prepared daily or more often if solution becomes diluted or soiled.

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

{Marketing Claims for all accepted formulas/CSFs}

{You can}[Use][Thymox® Disinfectant Spray][this product] [in] [on the following hard non-food, non-porous surfaces:][and] [locations]:

<p>(TABLE 1)</p> <p>[the kitchen]</p> <p>[the bathroom]</p> <p>[your house]</p> <p>[public areas]</p> <p>[the office]</p> <p>[Medical][Dental][Offices][Waiting room]</p> <p>[Health Care Facilities]</p> <p>[Clinics]</p> <p>[Hospitals]</p> <p>[Nursing Homes]</p> <p>[Day Care Center]</p> <p>[Nurseries]</p> <p>[Ambulances]</p> <p>[Institutional Kitchens]</p> <p>[Cafeterias]</p> <p>[Stores]</p> <p>[Restaurants]</p> <p>[Food Processing Plants]</p>	<p>[Public Restrooms]</p> <p>[Taxis]</p> <p>[Hotels and Motels]</p> <p>[Institutional facilities]</p> <p>[Correctional facilities]</p> <p>[Military Installations]</p> <p>[Schools]</p> <p>[Church]</p> <p>[Dormitory]</p> <p>[Classrooms]</p> <p>[Colleges]</p> <p>[Athletic facilities]</p> <p>[Shower and Bath areas]</p> <p>[Barber Shops, Beauty and Tanning Salons]</p> <p>[Airports/Airplanes]</p> <p>[Farms (Livestock; Dairy; Fruits and Vegetables)]</p> <p>[Zoos]</p>
---	---

{You can}[Use][Thymox® Disinfectant Spray][this product] [suitable for use] [on][any][all][hard, non-porous surfaces] [where] [bacteria][virus*][microbes][microorganisms] [germs*] [or] [strong] [unpleasant] [odors] [reside][are [usually] present] [are likely to be present] [are a concern][,] [including] [such as] [,]:

<p>(TABLE 2)</p> <p>[Countertops]</p> <p>[Stovetops]</p> <p>[Refrigerator exteriors]</p> <p>[Trash Cans] [Floors] [Garbage cans]</p> <p>[Children's][School][Toys] – rinse with potable water after application of Thymox® Disinfectant Spray]</p> <p>[Appliance exteriors]</p> <p>[Baby Furniture] [Changing tables] [Cribs]</p> <p>[Highchairs] [Diaper Pails]</p> <p>[Telephones] [Door handles]</p> <p>[Keyboards]</p> <p>[Grill exteriors]</p>	<p>[PPE (personal protective equipment)]</p> <p>[Hard, non-porous surfaces of Sinks]</p> <p>[Bathtubs]</p> <p>[Vanities]</p> <p>[Walls]</p> <p>[Windows]</p> <p>[Mirrors]</p> <p>[Toilet seats]</p> <p>[Hard sporting equipment]</p> <p>[Cups][Helmets]</p> <p>[Examination Tables] [Patient Chairs]</p> <p>[Tables][Doors]</p> <p>[Hard, Patio Furniture]</p> <p>[Pet Habitats (empty)]</p>
---	--

{The product} [it] [will not] [harm] [damage]

{Use on}[Safe on][hard][Non-porous] [materials][surfaces] [such as]:[,]:

<p>(TABLE 3)</p> <p>[Metal]</p> <p>[Glazed Ceramic]</p> <p>[Glazed Porcelain]</p> <p>[Glazed enameled surfaces]</p> <p>[Glass]</p> <p>[Sealed Marble]</p> <p>[Steel]</p> <p>[Stainless Steel]</p>	<p>[Brass]</p> <p>[Aluminum]</p> <p>[Sealed Concrete]</p> <p>[Plastic (such as polypropylene, polystyrene, polyethylene, PVC)]</p> <p>[Glazed Tile]</p> <p>[Sealed Fiberglass]</p> <p>[Sealed [or Varnished] wood]</p>
---	---

{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}

{NONREFILLABLE 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.

{HOUSEHOLD OR RESIDENTIAL CONTAINER INTENDED TO REFILLED WITH THIS PRODUCT BY USER}

STORAGE AND DISPOSAL

Store at room temperature [20-25C][68F-77F] in a secure area inaccessible to children. Do not reuse or refill this container except as described in the directions for use. Refill only with this product. 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. 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.

{CONTAINERS FOR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL USES – ALL SIZES, INTENDED TO REFILLED WITH THIS PRODUCT BY USER}

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: Do not reuse or refill this container except as described in the directions for use. Refill only with this product. If not refilling, 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]*
[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*]
[*Respiratory Syncytial Virus (RSV) *]
[in 1 minutes] [on hard, nonporous surfaces]

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

[Note to reviewer: The "+" qualifier is only required if "germs" claims are on container label.]

[Kills bacteria that can cause food poisoning*]
[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] [!][and leaves a fresh botanical scent]
[Cleans and Disinfects without bleaching]
[Free from] [chlorine] [.] [and] [or] [phosphate]
[Contains] [No] [Does not contain] [abrasives] [chlorine] [bleach] [harsh chemical] [residue]
[Bleach free] [Free from bleach] [no chlorine bleach] [bleach alternative]
[Non abrasive formula] [Non-Abrasive formula]
[Disinfects] [as it cleans] [while you clean]

[It's Both (A Heavy Duty Cleaner and Disinfectant)]
[Odor Eliminating] [with the Power of] [and] [Forever Fragrant]
[A] [Cleaning and Disinfecting Formula]
[Sreak-free] [Sparkling shine]
[Ready to Use [(R TU)]]
[A better way to clean]
[Kills][Eliminates] [odor causing bacteria]
[Try it on your mirrors.]
[Contains] [no Chlorine]
[Contains] [no Phosphates]
[Botanically derived] [active ingredient] [.] [kills cold and flu viruses*]
[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]
[Subtle Fragrance]
{Product scent name} [Orange Blossom] [Fresh Linen] [Warm Vanilla] [Spring Meadow]
[It] [Leaves a] [Fresh] [pleasant] [Thyme] [scent]
[It] [Leaves a] [pleasant] [Fresh] [and] [clean] [Thyme] {name of actual scent in product} [aroma]
[It] [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!] [3 min kill time]
[Kills bacteria, fungi and viruses*] [!]
[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}
[A] [great] [powerful] [Clean with No Compromises] [New Way to Clean with Power] [Perfect] [for keeping] [your home] [Keep a] [clean [home] for [your] family] [&] [and] [Pets] [Powerful clean without compromise] [Powerful clean without the problems] [Miracle in Cleaning Technology]
[All the clean, none of the worry]
[Don't compromise] [with] [your cleaning power]
[Patented power for a perfect clean]
[Driven by Thymox Technology]
[Clean] [perfectly] [smarter] [.] [with the power of science] [clean better] [redefined]
[Redefine] [Reimagine] [the meaning of clean] [the power of clean]
[Science that makes your world work]
[Stay smart, stay clean, stay happy]
[The power] [of a perfect clean] [of science] [.] [the power of clean] [Your clean on your terms]
[Pull back for instructions] [See inside label for complete Directions for Use]
[For heavily soiled surfaces, use with a non-scratch scrub sponge]
[It] [Kills Colds and Flu Viruses*] [Botanically]
[Suitable] [Great] [for] [to] [.] [use] [in] [around] [Family] [&] [and] [Pet] [s] [Cat] [or] [Dog] [areas]
[A] [new] [up to 6 months after date of first sale] [smart] [great] [powerful] [fast] [faster] [strong] [perfect] [better] [way to clean] [clean] [your home] [for your family] [&] [pets] [!]

{Optional Graphic – following graphic may or may not appear on label}



[Disinfectant Cleaner]
[Multi-Surface Cleaner]
[It][Cuts grease][&] [and] [grime]
[Driven by] [Thymox Technology][Inside][Thymox] [US PTO] [Worldwide] [Internationally] Patented
[technology] [formula] [formulation] [composition] [US 8,691,292 B2]
[Worldwide] [Internationally] [Patent protected] [in USA]
[Formulated][by][with][Thymox Technology]
[Don't Compromise!]

{Optional Marketing claims only for Basic CSF and Alternate 9 (formulas acceptable for surfaces that when dry may directly contact food)}

No [rinse][rinsing][required][needed] on food contact surfaces
On food contact surfaces, no [rinse][wipe] is required
Use on [food contact surfaces] [including [kitchen tables][appliances][high chair trays][and][insert any location, item, or surface material from Tables 1,2, or 3]No rinse required on [baby] [children's] toys and furniture
[Can be used on] [Baby Toys] [and] [Furniture]

{Optional Graphic / Logo}



{Optional - Good Housekeeping Seal}

{Optional - Graphics reflecting fragrance or accepted surfaces}



