

87742-1

12/27/2011

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

Number: 87742-1

Date of Issuance: DEC 27 2011

Term of Issuance: Unconditional

Name of Pesticide Product: Thymox Disinfectant Spray

NOTICE OF PESTICIDE:
[X] Registration
[] Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Laboratoire M2
4005-A Rue de la Garloac, Sherbrooke
Quebec, J1L W9 CANADA

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product (OPP Decision Number: D-452952) is unconditionally registered in accordance with FIFRA sec 3(c)(7)(a) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
a. Revise the EPA Registration Number to read, "EPA Reg. No. 87742-1".
b. Revise the 1st claim on page 2 to read "You can use Thymox disinfectant Spay [this product] [in][on the following hard non-food, non-porous surfaces:]"
c. Revise the surface, Appliances, on page 2 to read "Appliance exteriors" since this product is for use on non-food contact surfaces.

Signature of Approving Official:

[Handwritten Signature]

Date:

DEC 27 2011

CONCURRENCES

Table with columns for SYMBOL, SURNAME, and DATE, containing names like Jacqueline Campbell and EPA Form 8570-6.

- d. Revise the "To Disinfect" directions on page 6 and the "Farm Premise/Veterinary Use" directions on page 7 by bracketing the contact time phrase for fungi, bacteria, and viruses by stating "[3 minutes to eliminate fungi], [2minutes to eliminate bacteria], and [1 minute to eliminate viruses]."
- e. Revise the 1st statement under the "To Sanitize" directions on page 6 to incorporate the organisms that it has been tested to mitigate by stating "This product is effective as a Non-Food Contact Sanitizer on hard nonporous surfaces against Enterbacter aerogenes and Staphylococcus aureus 30 seconds."
- f. Revise the 6th step under "Farm Premises and Veterinary Use" directions on page 7 by deleting the term, recommended."
- g. Revise the last statement of the "Household/Residential Storage and Disposal" instructions on page 8 by adding the phrase, "or discard in the trash."
- h. Revise the second to last statement under the "Refillable Storage and Disposal" on page 8 by adding the phrase, "For final container disposal: offer for recycling or reconditioning if appropriate, or ..."
- i. The species name for the organism, Klebsiella, on page 9 is spelled incorrectly. Revise to read "Klebsiella pneumonia."
- j. An unqualified "Botanical" claim is unacceptable and is considered false and misleading under 40 CFR 152.10. Therefore, delete "botanical" on page 9 and revise the claim on page 10 to read "Botanically derived active ingredient."
- k. Revise the 10th claim on page 10 by deleting the term, Powerful, because it implies heighten efficacy per PR Notice 93-6.

3. Submit a 1 year storage stability and corrosion characteristics study in accordance with OPPTS 830.6317 and 830.6320 guidelines a year from the date of this notice.

4. A stamped label with comments is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6416 or Stacey Grigsby at (703) 305-6440.

Sincerely,

Jacqueline Campbell
CONCURRENCES Product Manager (34)

Regulatory Management Branch II
Antimicrobials Division (7510P)

| | | | | | | | |
|---------|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

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

{Master Label}

Thymox ® Disinfectant Spray {on front label}

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

Keep Out Of Reach Of Children {on front label}

[CAUTION {on front label}]

ACTIVE INGREDIENT:

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

OTHER INGREDIENTS:..... 99.77%

Total..... 100.00%

{on front label}

{The contents, in US measurement, will appear on the front label}

Net content [XXX] fl oz [xxx mL]

EPA Reg. No. 87742-X

EPA Est. No. 87742-CAN-001

Manufactured by

Laboratoire M2

4005-A, Rue de la Garlock, Sherbrooke

Québec, J1L 1W9 CANADA

ACCEPTED
with COMMENTS
EPA Reviewer's Initials:

DEC 27 2011

Made in {country}

Manufactured for {name of distributor}

{address of distributor}

[[phone number of distributor]]

[[website of distributor]]

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

87742-1

{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}

[You can][Use][Thymox® Disinfectant Spray][this product] [in] [on hard 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] [Cafeterias] [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] |
|--|--|

[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] [:][.]

| | |
|---|--|
| [Countertops] [Stovetops] [Refrigerator exteriors] [Trash Cans] [Floors] [[Children's][School][Toys] – rinse with potable water after application of Thymox® Disinfectant Spray] [Appliances] [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] |
|---|--|

{All text in brackets [] is optional and may or may not appear on the printed label}
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PRODUCT : Truymox® Disinfectant Spray
EPA Reg. No. : 87742-X

[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] |
|---|---|

{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.

{All text in brackets [] is optional and may or may not appear on the printed label}

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

[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] [Fungicidal] [according to the AOAC Germicidal Spray Method] [and] [Virucidal*] [according to the ASTM Standard Test Method for Efficacy of Virucidal Agents][.]

[The efficacy of] [Thymox® Disinfectant Spray] [this product] [was shown in the presence of 5% organic serum] [.] [against][:] [is 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 [S.] 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].

{All text in brackets [] is optional and may or may not appear on the printed label}
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{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.]

{All text in brackets [] is optional and may or may not appear on the printed label}

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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] [and 1 minute] [to eliminate] [viruses*] [,] [Allow to air dry.] [If desired, wipe dry.]

{One of the following statement 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.

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{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.

{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 ~~recommended~~ 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.]

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100412

PRODUCT : T...nox® Disinfectant Spray
EPA Reg. No. : 87742-X

{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.

{NONREFILLABLE CONTAINERS FOR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL USES - ALL SIZES}
STORAGE AND DISPOSAL
Do not contaminate water, food or feed by storage and 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 and 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. 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.

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110912

PRODUCT : ~~Tri~~nox® Disinfectant Spray
EPA Reg. No. : 87742-X

[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 pneumonia – NDM-1 positive] [K. pneumonia 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]

[~~Botanical~~] [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 in1 Household Cleaner & Disinfectant]
[One Step Cleaner & Disinfectant]
[Disinfects and cleans] [!] [at the same time]
[Deodorizes]

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[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]
 [~~Powerful~~ 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]

[~~Botanical~~]
 [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!]
 [Inventor]{Laboratoire M2 Logo}

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