

56392-2

02-05-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

FEB - 5 2010

Mr. David Swain
Agent for Caltech Industries, Inc
SRC Consultants, Inc
PO Box 1014
Columbia City, IN 46725

Subject: Citrace Hospital Germicide
EPA Registration No.: 56392-2
Amendment Date: November 12, 2009
EPA Receipt Date: November 13, 2009

Dear Mr. Swain,

The following amendment submitted in connection under the provisions of FIFRA, as amended, is acceptable with conditions listed below.

Proposed Amendment

Adding Pandemic H1N1 Influenza A claims

Conditions

Revise the label as follows:

- 1.) The Agency has determined that the "air deodorization" use is false and misleading according to FIFRA 3(c)9 and 40 CFR 156.10(a)(5) because it implies to the user that the product would provide pesticidal benefits to sites/surfaces for which a pesticidal claim has not been substantiated. Therefore, delete the "Destroy/Eliminate Odors" directions on page 2.
- 2.) Revise the "To Clean" and "To Control Mold/Mildew on Fabric" headings on pages 2 and 3 to read "To Clean/Deodorize" and "To Control Mold/Mildew and Deodorize on Fabrics." This revision supports the "Destroys Odors" claim at the top of page 2.
- 3.) Revise the "Personal Protection" statement under HIV-1 directions by deleting the term, or, and stating "and." The personal protection items are not optional when handling blood and body fluids.

4.) The "Disposal of Infectious Materials" ~~statements~~ under HIV-1 directions must be brought into compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, should, and stating "must."

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5.) Since this product is for use in veterinary clinics, you must add the following directions:

To Disinfect Veterinary Offices/Clinics: Remove all animals and feed from premises, vehicles, cages, kennels, etc. Remove all litter, droppings, and manure from floors, walls, and surfaces of facilities occupied or traversed by animals. Empty all feeding and water appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Hold container upright about 6-8" from surface. Spray to thoroughly wet hard, nonporous surfaces. Treated surfaces must remain wet for 5 minutes. Allow to air dry. Immerse all halters, collars, leashes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, vehicles, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub feeding and watering equipment with soap or detergent, and rinse with potable water before reuse.

6.) Since this product may be used to disinfect toilets and urinals, you must add the following directions:

To Disinfect Toilets and Urinals: Remove gross filth prior to disinfection. Empty toilet bowl or urinal. Hold container upright about 6-8" from surface. Spray to thoroughly wet hard, nonporous surfaces. Brush over exposed surfaces and under the rim. Allow to stand for 5 minutes, then flush.

7.) Delete the 14th claim, "Environmentally sensitive friendly packaging." The Factual Statements Pilot allows recycling packaging claims; it does not extend to "environmentally safe/sensitive" packaging claims.

8.) Delete the 20th, 21st, and 22nd claims on page 4 because it is false and misleading according to 40 CFR 156.10. These claims imply that the product's efficacy extends beyond surface disinfection/sanitization but to an individual's and/or public's health. The use of the term, health, makes these claims under FDA's purview.

9.) The 24th, 25th, and 26th claims on page 4 must be revised by deleting the term, "Safely."

10.) Delete the 27th claim.

11.) Delete the 28th, 30th, and 31st claims on page 4 and 1st, 2nd, 3rd, 6th, 9th, 10th, 11th, 12th, 13th, and 14th claims on page 5 because they are false and misleading according to 40 CFR 156.10. These claims imply that this product imparts bacterial, viral, fungicidal protection against the organisms listed on the label to users not the surfaces. These claims are considered drug claims which are under the purview of FDA not EPA.

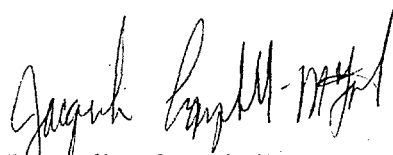
General Comments

A stamped accepted label with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

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Should you have further questions concerning this letter, please contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 308-6440 or by email at grigsby.stacy@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Jacqueline Campbell-McFarlane
Acting Product Manager (PM-34)
Regulatory Management Branch 2
Antimicrobials Division (7510P)

Enclosure: Stamped Label

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CITRACE® HOSPITAL GERMICIDE

- [[Citrus][Orange] Scent]
- [Kills Germs that Cause Odors]
- [[Eliminates][Destroys] Odors]
- [One-Step Disinfecting]
- [Effective against Antibiotic Resistant [Microorganisms][*Bacteria*][in 5 Minutes][*(MRSA, VRE, VRSA, PRSP)*]]
- [[Sanitizes][Kills][Reduces] 99.9% of *Bacteria* in 30 Seconds*]
- [[Controls][Inhibits][Prevents] Mold & Mildew on Fabrics]
- [Lower [VOC] [(Volatile Organic Compound)] Content]
- [Kills Pandemic 2009 H1N1 influenza A virus]

Kills bacteria, viruses[†], & fungi on hard, non-porous surfaces

In 1 MINUTE: [[†]HIV-1] [(AIDS Virus)] [and] [[†]Hepatitis B Virus] [(HBV)]

In 5 MINUTES: *Acinetobacter baumannii*, [†]Adenovirus [Type 2], [†]Avian Influenza A strain H5N1, [†]Canine Parvovirus, [†]Coxsackie Virus, *Enterobacter aerogenes*, *Enterococcus faecalis* [Vancomycin resistant] [(VRE)], *Escherichia coli* ESBL, [†]Hepatitis A Virus [(HAV)], [†]Herpes Simplex Virus [(HSV-1)], [†]Influenza A Virus, *Klebsiella pneumoniae*, [†]Poliovirus, *Pseudomonas aeruginosa*, [†]Respiratory Syncytial Virus [(RSV)], [†]Rhinovirus, [†]Rotavirus, *Salmonella enterica*, *Staphylococcus aureus*, *Staphylococcus aureus* [Methicillin resistant] [(MRSA)], *Staphylococcus aureus* [[Methicillin resistant] [Community Associated]] [(CA-MRSA)] [(Genotype) USA 400], *Staphylococcus aureus* [[Methicillin resistant] [Community Associated]] [(CA-MRSA)] [(Genotype) USA 300], *Staphylococcus aureus* [Vancomycin resistant] [(VRSA)], *Streptococcus pneumoniae* [Penicillin resistant] [(PRSP)], *Streptococcus pyogenes*, *Trichophyton mentagrophytes* [(Athlete's Foot Fungus)], [†]Vaccinia Virus

Active Ingredients:

o-Phenylphenol.....	00.13%
Ethanol.....	66.34%
Other Ingredients.....	33.53%
TOTAL.....	100.00%



Contains no CFCs or other ozone depleting substances.
Federal regulations prohibit CFC propellants in aerosols.

RECEIVED
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563922

KEEP OUT OF REACH OF CHILDREN
CAUTION
READ COMPLETE PRECAUTIONS AND
DIRECTIONS [ON REAR PANEL(S)][INSIDE BOOKLET]
 Net Contents

Manufactured for:
 © XXXX Caltech Industries, Inc.
 4520 E. Ashman, Midland, MI 48642
 300-234-7700 www.caltechindustries.com
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EPA Reg. No. 56392-2
 EPA Est. Nos. 33915-MI-1^F
 62801-MI-1^F
 (Superscript used is second letter of Lot No.)

Note: Bracketed [] information is optional text. {Bracketed Text} is for administrative purposes only and will not appear on the printed label.

[CITRACE® HOSPITAL GERMICIDE]

DESTROYS ODORS: [This effective product] eliminates odors at their source by killing germs that cause odor. Does not just mask odors. May be used to eliminate odors retained in fabrics, draperies, or upholstered furniture.

KILLS GERMS: Disinfects by killing microorganisms on hard, non-porous environmental surfaces such as stainless steel, chrome, plastic, glazed porcelain, and mirrors. [Inhibits] [Controls] mold and mildew. Meets OSHA bloodborne pathogen standards. ***Sanitizes** by killing 99.9% of *Staphylococcus aureus* and *Klebsiella pneumoniae* on hard, non-porous surfaces.

CONTROLS MOLD AND MILDEW: [This product] [inhibits] [prevents] [controls] mold and mildew on fabrics [such as curtains, mattresses, pillows, and upholstery].

Use Sites: [For use in] homes, hospitals, clinics, schools, long-term care facilities, physician offices, dental offices, [and] veterinary facilities. [Use this product in] patient [isolation] [treatment] rooms and waiting areas, emergency rooms, outpatient facilities, exam rooms, laboratories, operator, radiology, physical therapy, central supply, and bathrooms.

Applications: [For] [non-critical][medical][equipment][including] supply carts, empty waste cans and laundry hampers, bathroom basins, urinal and toilet areas, bed frames and springs, wheelchairs, walkers, and high-touch surfaces such as telephones, TV remotes, countertops, light switches, and door knobs.

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

~~**TO DESTROY [ELIMINATE] ODORS:** Shake well. Hold can upright. Spray 1-2 seconds. For a moment there's the fresh smell of [orange] [citrus] and then it disappears quickly, taking unpleasant odors with it.~~

TO CLEAN: Shake well. Spray lightly and immediately wipe dry with cloth or paper towel. Effective as a light duty cleaning agent to remove fingerprints and hand smudges.

TO SANITIZE: Shake well. Hold can upright 6" - 8" from surface. Spray surface until thoroughly wet. Let stand for 30 seconds. Allow to air dry or wipe dry. [Gross] [Heavy] soil must be removed prior to sanitizing.

TO DISINFECT: Shake well. Hold can upright 6" - 8" from surface. Spray non-porous surface until thoroughly wet. Let stand for 5 minutes. Allow to air dry or wipe dry. [Gross] [Heavy] soil must be removed prior to disinfecting.

[Efficacy] [Independent lab] tests have demonstrated that this product is an effective bactericide, virucide, and fungicide in the presence of organic soil (5% blood serum).

Kills HIV-1 (AIDS Virus) and HBV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare 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 Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) and Hepatitis B Virus (HBV). **Special Instructions for Cleaning and Decontamination Against HIV-1 (AIDS Virus) and HBV on Surfaces/Objects Soiled with Blood/Body Fluids: Personal Protection:** When handling items soiled with blood/body fluids, appropriate personal protective equipment such as disposable plastic gloves, gowns, masks, eye coverings should be considered. **Cleaning Procedure:** Blood/body fluids must be thoroughly cleaned from surfaces and objects prior to disinfecting. **Contact Time:** This product kills HIV-1 (AIDS Virus) and HBV in 1 minute. Contact time required to kill other organisms is 5 minutes. **Disposal of Infectious Materials:** Blood/body fluids and cleaning materials should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

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TO CONTROL MOLD AND MILDEW ON FABRIC: Shake well. Hold can upright 6" – 8" from surface. Spray surface until thoroughly wet and repeat [monthly] to prevent regrowth.

{One of the following two statements will be present on the final printed label:}

This product is not for use on critical or semi-critical medical device surfaces.

or

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.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage and disposal.

Storage: Do not use or store near heat or open flame. Store out of reach of children.



Disposal: This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to the label [(if can stops spraying before empty, turn cap until spray restarts)]. (DO NOT PUNCTURE!) If recycling is not available, wrap the container and discard in the trash.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Do Not Spray in Eyes. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

FIRST AID: IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes.

Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call the National Poison Control Center at 800-222-1222 or a doctor for treatment advice. Have the product with you when calling a poison control center or doctor or going for treatment.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

Before using on painted or plastic surfaces, spot test on an inconspicuous area. Not recommended for use on acrylic plastics or vinyl.

REORDER NO.

See Expiration Date on [Package][Can]

{*Optional Text. May be placed anywhere on the label/container*}

Delivery system reduces waste/overuse.

[Lower] [Reduced] VOC[s] (Volatile Organic Compound[s]) [content].

Recyclable cardboard cartons.

Note: Bracketed [] information is optional text. {*Bracketed Text*} is for administrative purposes only and will not appear on the printed label.

Orange scent
For Hard, Non-Porous Surfaces [in Hospitals and Clinics].
Kills *Bacteria*, Viruses, and *Fungi* in 5 Minutes. [(See [listing] [on]-rear panel)[inside booklet])]
[Unique][Controlled][Low][Flow] Spray [Rate]
Fresh [light][fast][dispersing] scent
Kills germs that cause odor
[No fog][Pressurized] spray
[Kills][eliminates] a broad spectrum of [microorganisms][organisms]
Cardboard and steel packaging are 100% recyclable
[100%] recyclable packaging
~~Environmentally sensitive friendly packaging~~
[Can] sprays [at least] 1.5 times longer [than others in the [product] category]
Delivery similar to a liquid trigger spray[er]
Does not fog
[fast [acting]] disinfecting
[Low][no] residue [upon drying]
~~[key][component of] Travel [Health] solution~~
~~[key][component of] Cruise [ship] [Health] solution~~
~~[key][component of] Office [Health] solution~~
[key][component of] bathroom solution
~~[Safety] freshens fabrics~~
~~[Safety] refreshes fabrics~~
~~[Safety] deodorizes fabrics~~
~~Safe for fabrics~~
Will not harm fabrics
[A][CITRACE®]Prevention Solution
~~[CITRACE®]Viral Prevention Solution™~~
[CITRACE®] Fabric Solution™
[CITRACE®] Cross Contamination Solution™ for Fabrics
~~[CITRACE®] Mildew Prevention Solution™ for Fabrics~~
~~[Key Component] of CITRACE® Viral Prevention Solution™~~
~~[Part][Component] of CITRACE® Viral Prevention Solution™~~
~~[CITRACE®]Bacterial Prevention Solution~~
~~[CITRACE®]Fungus Prevention Solution~~
~~[CITRACE®]Mold [and] [Fungus] Mildew Prevention Solution~~
[CITRACE®]Odor Solution
[CITRACE®] [Hospital][Home Care][Out Patient] High[-]Touch Surface Solution
~~[CITRACE®] [Hospital][Home Care][Out Patient] Cold [and] [Flu] [Prevention] Solution~~
[CITRACE®] [Hospital][Home Care][Out Patient] Solution
[CITRACE®] [Hospital][Home Care][Out Patient] Odor Solution
~~[CITRACE®] [Hospital][Home Care][Out Patient] Prevention Solution~~
~~[CITRACE®] [Hospital][Home Care][Out Patient] Viral Prevention Solution™~~
~~[CITRACE®] [Hospital][Home Care][Out Patient] Bacterial Prevention Solution~~
~~[CITRACE®] [Hospital][Home Care][Out Patient] Bacterial Prevention Solution~~
~~[CITRACE®] [Hospital][Home Care][Out Patient] Fungus Prevention Solution~~
~~[CITRACE®] [Hospital][Home Care][Out Patient] Fungus Prevention Solution~~
Bactericidal
Fungicidal

Note: Bracketed [] information is optional text. {Bracketed Text} is for administrative purposes only and will not appear on the printed label.

Virucidal
DOT2Q

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. [This product] [Product Name] 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] [Product Name] has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

[This product] [Product Name] 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)

Additional Use Sites:

- blood banks
- day care centers
- industrial buildings
- pharmacy
- public places
- [public] restrooms
- reception areas

Additional Applications:

- bidets
- blood pressure [sets] [cuffs]
- clean-up carts
- counters (non-wood)
- desks
- diaper changing tables
- diaper pails
- examination tables
- glass
- glass-topped furniture
- glazed ceramic tile
- handrails
- hard [plastic] surfaces
- hard [solid] surfaces
- keyboards
- laminated [surfaces]
- patient chairs
- plastic mattress covers
- refrigerator handles
- remote controls
- shower [stalls] [area] [doors]
- sinks

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stethoscopes
stretchers
supply carts
Thera-bands®
toilets
toilet areas
toilet seats
water fountain handles