

56392-2

4/15/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

David Swain  
Agent for Caltech Industries, Inc.  
Scientific & Regulatory Consultants, Inc.  
P.O. Box 1014  
Columbia City, IN 46725

APR 15 2009

Subject: **Citrace® Hospital Germicide**  
EPA Registration Number: 56392-2  
Application Date: November 24, 2008  
Receipt Date: November 25, 2008

Dear Mr. Swain

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below:

**Proposed Amendment**

- Revised Basic and Alternate Confidential Statement of Formulas (CSFs) #1 and # 2
- Addition of public health organisms

**Label Comments**

1. Under the "To Sanitize" directions on page 2, change "Allow to air dry or wipe dry" to read "Allow to air dry or wipe dry. Gross soil must be removed prior to sanitizing."
2. Delete claim [for up to 28 days] in the Controls Mold and Mildew section and claim for [every 28 days] in the To Control Mold and Mildew On Fabric section, you may submit efficacy data at a later date to add this claim.
3. Remove [Useful] from the Applications section of page 2 and revise to read [For] non-critical.. Refer to PR Notice 2000-5 for mandatory language.
4. Revise Storage and Disposal section as follows:

**Storage and Disposal**

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

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

**Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental control Agency, or the Hazardous Waste representative at he nearest EPA Regional Office for guidance.

**“Container Disposal:** Nonrefillable container. Do not reuse or refill this container. This container may be recycled in aerosol recycling centers.....” The proposed disposal statement must be incorporated into this section.

### Acceptable Data (Efficacy)

Data Requirement	Means of Support	Status
<i>Acinetobacter baumannii</i>	Submitted study, MRID 476071-02	Acceptable, in 5% organic soil for 5 minutes
Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> (NARSA NRS123) (Genotype USA400)	Submitted study, MRID 476071-03	Acceptable, in 5% organic soil for 5 minutes
Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> (NARSA NRS384) (Genotype USA300)	Submitted study, MRID 476071-04	Acceptable, in 5% organic soil for 5 minutes
<i>Enterobacter aerogenes</i>	Submitted study, MRID 476071-05	Acceptable, in 5% organic soil for 5 minutes
<i>Escherichia coli</i> with extended beta-lactamase resistance	Submitted study, MRID 476071-06	Acceptable, in 5% organic soil for 5 minutes
<i>Klebsiella pneumoniae</i>	Submitted study, MRID 476071-07	Acceptable, in 5% organic soil for 5 minutes
<i>Staphylococcus aureus</i> - MRSA	Submitted study, MRID 476071-08	Acceptable, in 5% organic soil for 5 minutes
<i>Streptococcus pneumoniae</i> Penicillin resistant	Submitted study, MRID 476071-09	Acceptable, in 5% organic soil for 5 minutes
<i>Enterococcus faecalis</i> Vancomycin Resistant	Submitted study, MRID 476071-10	Acceptable, in 5% organic soil for 5 minutes
Vancomycin Resistant <i>Staphylococcus aureus</i> (NARSA VRS1)	Submitted study, MRID 476071-11	Acceptable, in 5% organic soil for 5 minutes
Adenovirus type 2	Submitted study, MRID 476071-12	Acceptable, in 5% organic soil for 5 minutes
Avian influenza A (H5N1) virus	Submitted study, MRID 476071-13	Acceptable, in 5% organic soil for 5 minutes
Coxsackievirus type A16	Submitted study, MRID 476071-14	Acceptable, in 5% organic soil for 5 minutes
Hepatitis A virus	Submitted study, MRID 476071-15	Acceptable, in 5% organic soil for 5 minutes
Hepatitis A virus.	Submitted study, MRID 476071-16	Acceptable, in 5% organic soil for 5 minutes
Rotavirus	Submitted study, MRID 476071-17	Acceptable, in 5% organic soil for 5 minutes
<i>Staphylococcus aureus</i> <i>Klebsiella pneumoniae</i>	Submitted study, MRID 476071-18	Acceptable, in 5% organic soil for 30 seconds

Please see the attached DER for additional details regarding the review of the submitted data.

**Data Matrix**

The following efficacy citation has been added to your data matrix 47442702. Please make the same correction to the data matrix in your files.

**Chemistry Data**

The following Product Chemistry study has been submitted: 476071-01. The study was reviewed and found to be acceptable in support of this formulation. Please see the attached DER for additional details.

The revised basic confidential Statement of Formula (CSF) dated 11/24/08 supersedes all previously accepted basic formulas. A copy of the accepted alternate CSFs #1 and 2 dated 11/24/08 have been inserted in your file for future reference.

**General Comments**

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

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

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6415 or email address at: [lantz.tracy@epa.gov](mailto:lantz.tracy@epa.gov), or Lisa McKelvin by telephone at (703) 308-7496 or email address at: [mckelvin.Lisa@epa.gov](mailto:mckelvin.Lisa@epa.gov).

Sincerely,



Tracy Lantz  
(Acting) Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Enclosed: Stamped label  
Efficacy DER (D: 359498) dated 2/27/09  
Product Chemistry DER (D:359496) dated 3/4/09



**CITRACE® HOSPITAL GERMICIDE**

- [Orange Scent]
- [Eliminates Odors]
- [One-Step Disinfecting]
- [Effective Against Antibiotic-Resistant [Microorganisms][Bacterial]]
- [[Sanitizes][Kills][Reduces] 99.9% of Bacteria in 30 Seconds\*]
- [Controls Mold & Mildew on Fabrics]
- [Lower [VOC] [(Volatile Organic Compound)] Content]

**Kills bacteria, viruses<sup>†</sup>, & fungi on hard, non-porous surfaces**

**In 1 MINUTE:** <sup>†</sup>[HIV-1] [(AIDS Virus)] and <sup>†</sup>Hepatitis B Virus [(HBV)]

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

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.

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**  
**READ COMPLETE PRECAUTIONS AND DIRECTIONS ON REAR PANEL[S]**  
Net Contents

**ACCEPTED**  
**with COMMENTS**  
**in EPA Letter Dated:**

**APR 15 2009**

**Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 56392-2**

Manufactured for:  
© 2008 Caltech Industries, Inc.  
4520 E. Ashman, Midland, MI 48642  
1-800-234-7700 [www.caltechindustries.com](http://www.caltechindustries.com)  
® Trademark of Caltech Industries, Inc.

EPA Reg. No. 56392-2  
EPA Est. Nos. 33915-MI-1<sup>F</sup>  
62801-MI-1<sup>F</sup>

(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][for up to 28 days].

**Use Sites:** [For use in] hospitals, clinics, 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, operatory, radiology, physical therapy, central supply, and bathrooms.

**Applications:** [Useful for] non-critical medical equipment including supply carts, empty waste cans and laundry hampers, bathroom basins and urinals, 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 ELIMINATE ODORS:** Shake well. Hold can upright. Spray 1-2 seconds. For a moment there's the fresh smell of orange and then it disappears quickly, taking unpleasant odors with it.

**TO DISINFECT:** Shake well. Hold can upright 6" - 8" from surface. Spray non-porous surface until thoroughly wet. Let stand 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, or 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.

**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.

**TO CONTROL MOLD AND MILDEW ON FABRIC:** Shake well. Hold can upright 6" - 8" from surface. Spray surface until thoroughly wet and repeat [every 28 days] [monthly] to prevent regrowth.

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

{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 pre-clean 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. Nonrefillable container. Do not reuse or refill this container.

**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 (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]

NFPA: HEALTH 0 FLAMMABILITY 3 REACTIVITY 0 SPECIFIC (NONE)

- 0 = NONE
- 1 = SLIGHT
- 2 = MODERATE
- 3 = HIGH
- 4 = EXTREME

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{Optional Claims. They 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.

Orange scent.

For Hard, Non-Porous Surfaces [in Hospitals and Clinics]. {Relocated from page 1 bullet points}

Additional Use Sites:

- blood banks
- day care centers
- industrial buildings
- pharmacy
- public places
- (public) restrooms
- schools

Additional Applications:

- bidets
- blood pressure sets
- clean-up carts
- counters (non-wood)
- desks
- diaper changing tables
- diaper pails
- examination tables
- glass
- glass-topped furniture
- glazed ceramic tile
- hard (plastic) surfaces
- hard (solid) surfaces
- laminated (surfaces)
- patient chairs
- plastic mattress covers
- remote controls
- shower (stalls) (area) (doors)
- sinks
- stretchers
- toilets
- toilet areas
- toilet seats

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