

56392-2

10/01/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 1, 2008

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

Subject: **Citrace® Hospital Germicide**
EPA Registration No. 56392-2
Application Dated: June 6, 2008
Receipt Date: June 9, 2008

Dear Mr. Swain:

The following amendment, submitted in connection with registration under section of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable.

Proposed Amendment:

- Reduce contact time and change directions to "one-step disinfection;
- Revised basic & alternate Confidential Statement of Formulas (CSFs), see CSF dated 6/06/08

Other comments:

The Agency is moving away from review of paper submitted registration applications to electronic review of applications. Therefore, we need your help to make this an efficient and convenient process for both you and the Antimicrobials Division. Accordingly, we are asking you to submit future labeling amendments for this product via the electronic labeling process. Refer to the following website for guidance on electronic submissions, including label:
<http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm>. If you have questions concerning electronic labeling, a list of contacts is available at the following site:
<http://www.epa.gov/opptead1/eds/edsgoals.htm#contacts>.

Copies of the basic and alternate CSFs have been inserted in your file for future reference. The basic CSF dated June 6, 2008 supersedes all previously accepted ones. A stamped copy of the accepted labeling is enclosed.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6422 or email address at: heyward.adam@epa.gov, or Renae Whitaker telephone at (703) 308-7003 or email address at: whitaker.renae@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: EPA stamped approved labeling



CITRACE® HOSPITAL GERMICIDE

- [Orange Scent]
- [Eliminates Odors]
- [One-Step Disinfecting]
- [For Hard, Non-Porous Surfaces [in Hospitals and Clinics]]
- [New and Improved] [Lower VOC [(Volatile Organic Compound)] Content] {“New and Improved” used for 6 months after approval}
- [Kills Rhinovirus in 5 minutes]

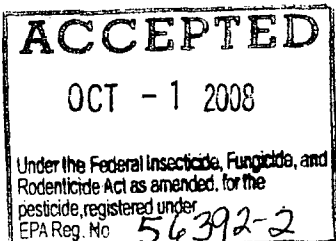
Kills HIV-1 (AIDS Virus) and Hepatitis B Virus (HBV) in 1 MINUTE

Kills bacteria, viruses†, & fungi in 5 MINUTES:

†Canine Parvovirus, †Herpes Simplex Virus (HSV-1), †Influenza A Virus, †Poliovirus, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, †Rhinovirus, *Salmonella enterica*, *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.

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ COMPLETE PRECAUTIONS AND DIRECTIONS ON REAR PANEL[S]

Net Contents

EPA Reg. No. 56392-2
© 2008 Caltech Industries, Inc.
Manufactured for: Caltech Industries, Inc.
4520 E. Ashman, Midland, MI 48642
1-800-234-7700 www.caltechindustries.com
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EPA Est. Nos: 33915-MI-1^J
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

This effective product eliminates odors at their source. Does not just mask odors. Kills micro-organisms on environmental surfaces such as stainless steel, chrome, plastic, glazed porcelain, and mirrors. [(See front panel)]. Inhibits mold and mildew. Meets OSHA bloodborne pathogen standards. FOR USE IN HOSPITALS, CLINICS, LONG-TERM CARE FACILITIES, PHYSICIAN OFFICES, DENTAL OFFICES, AND VETERINARY FACILITIES. Use this product in patient rooms and waiting areas, emergency rooms, outpatient facilities, exam rooms, laboratories, operator, radiology, physical therapy, central supply, and bathrooms. Useful for non-critical medical equipment 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 surface 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 nonporous surface until thoroughly wet. Allow 5 minutes contact time. Allow to air dry or wipe dry. Gross soil must be removed prior to disinfecting.

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 CONTROL MOLD AND MILDEW: Shake well. Clean surface prior to application. Spray surface until thoroughly wet and repeat weekly to prevent regrowth. Provides residual bacteriostatic action in the presence of moisture.

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{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. 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 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.

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REORDER NO. 49100

UPC 7 29969 49100 0

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

{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.