

70144-1

2/11/2008

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

RegWest
Agent for Micro-Scientific Industries, Inc.
30856 Rocky Road
Greeley, CO 80631-9375

FEB 11 2008

Attention: Kim Davis
Regulatory Manager

Subject: Opti-Cide 3
EPA Reg. No. 70144-1
Amendment Application Date: May 30, 2007
EPA Received Date: May 31, 2007

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided the following label revisions are inserted:

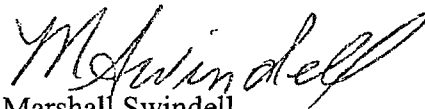
- There are currently no registered products that have claims as disinfectant used in ventilation systems (the use site listed in your reference label). Efficacy data needs to be submitted to support these claims. EPA requires that registrants proposing this claim submit an acceptable test method that shows the product is effective in treating pathogenic organisms in ventilation systems.
- Use sites listed that make reference to treatment of "food preparation surfaces (with potable water rinse)" need to be removed. "This disinfection claim is not supported by data. In addition, this use needs Food and Drug Administration approval before it can be added to this label.
- For the listed use sites "refrigerators" and "warmers", in parentheses, add the wording (exterior surface).
- Before the listed use site "ship [river, ocean, sea vessel, add the wording "interior surfaces of"
- The Agency request that you delete the *C. difficile* claim from your label. The Agency has re-evaluated its acceptance of *Clostridium difficile* (vegetative form)

on previously accepted claims and requests for new claims. Peer-reviewed scientific literature and case studies have consistently demonstrated that the *C. difficile* spore is the source of *Clostridium difficile*-associated disease (CDAD), and is an immediate public health concern. After careful consideration, the Agency is certain that claims against the vegetative form of *C. difficile* are misleading (40 CFR 156.10(a) (5), and imply heightened efficacy. The Agency considers antimicrobial pesticides to be unique because of the critical nature of the threat to public health that may result from ineffective use of products due to obsolete or misleading labeling. As a result, any reference to claims of effectiveness against *Clostridium difficile* (vegetative) OR *Clostridium difficile* (without having supporting data against *C. difficile* spores) are unacceptable. To address the growing need for products in hospital/medical setting, the Agency is moving expeditiously to develop an appropriate test system and performance standards for *Clostridium difficile* (spores).

- All references to the wording "et cetera" (etc) and "other" needs to be removed. A reference such as this word is broad and could imply a variety of meanings or interpretations.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,



Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

Opti-Cide® 3

Veterinary/Animal/Pet Care Facility Disinfectant/Cleaner
Barber/Salon [Clipper Blade] Disinfectant/Cleaner
Disinfectant/Decontamination Cleaner
Surface Disinfectant/Decontamination Cleaner
Medical/Surgical/Dental Equipment Disinfectant Cleaner and Decontaminant
Bactericidal • Fungicidal • Virucidal* • Tuberculocidal
Ready-to-Use

Disinfectant Cleaner [and] Deodorizer

Disinfects Cleans Deodorizes

Kills Bacteria, Viruses, Fungi, Mycobacterium Tuberculosis [in 3 minutes]

Kills Bacteria – Viruses – Fungus on hard, non-porous surfaces such as Litter Boxes, Kennels, Cages
And For Spot Cleaning

With [Contains] Fresh [or other appropriate descriptive term] Scent

With [Contains] Rust Inhibitor, Biodegradable Detergent

For [Use on] Pet Care Surfaces

[Surface/Facility] {description taken from use directions} Disinfectant Cleaner

[For Professional Use]

Active Ingredients:

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chloride	0.154%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl	
ammonium chloride	0.154%
Other Ingredients	99.692%
Total	100.000%

Keep Out of Reach of Children

CAUTION

See back [side] panel for additional precautionary statements.

EPA Reg. No. 70144-1 EPA Est. 1130-IL-1

Net Contents: _____ oz. (_____ ml)

Product Order Number: _____

{flag graphic}

Made in the U.S.A.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 11 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
amended, for the pesticide,
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{Back/Side Panel(s)}

Opti-Cide 3 effectively kills the following microorganisms at room temperature (69°F/20°C) with a 3-minute contact time:

[*Viruses:] Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex II Virus (HSV-2) G⁺ Strain, Human Immunodeficiency Virus (HIV-1) (associated with AIDS), Influenza Virus Strain A2/Hong Kong, Polio I Virus ATCC VR-58, Rhinovirus ATCC VR-286 and Rotavirus Strain WA

[Mycobacterium:] *Mycobacterium bovis* BCG (tuberculosis) (TB)

[Gram Positive and Gram Negative Bacteria:] *Acinetobacter baumannii* (ATCC 19606)⁺, *Clostridium difficile* (vegetative) ATCC 9689, *Staphylococcus aureus* ATCC 6538, *Pseudomonas aeruginosa* ATCC 15442, *Salmonella enterica* ATCC 10708, Methicillin-Drug Resistant *Staphylococcus aureus* (MRSA) ATCC 33591 and *Enterococcus faecium* (VRE) ATCC 51559.

[Pathogenic Fungi:] *Trichophyton mentagrophytes* ATCC 9533

4047

Opti-Cide 3 effectively kills the following microorganisms with a 3-minute contact time at 69°F/20°C on hard, non-porous inanimate surfaces when used as directed: Avian Influenza A Virus ATCC VR-2072, *Bordetella bronchiseptica* (kennel cough) ATCC 10580, *Bovine Viral Diarrhea Virus (BVDV – Surrogate Hepatitis C Virus), Canine Distemper Virus ATCC VR-128, Canine Para-Influenza Virus ATCC VR-666, [REDACTED] ATCC 9689, Duck Hepatitis B Virus (DHBV – Surrogate Hepatitis B Virus), Feline Leukemia Virus, Herpes Simplex II Virus (HSV 2) G Strain, Infectious Bovine *Rhinotracheitis* Virus ATCC VR-188, Influenza Virus Strain A2/Hong Kong, *Mycobacterium bovis* BCG (tuberculosis) (TB), *Pseudomonas aeruginosa* ATCC 15442, Rhinovirus ATCC VR-286, Rotavirus Strain WA, *Salmonella enterica* ATCC 10708, *Staphylococcus aureus* ATCC 6538, Methicillin-Drug Resistant *Staphylococcus aureus* (MRSA) ATCC 33591, *Streptococcus equi* ATCC 33398, *Trichophyton mentagrophytes* (ringworm) ATCC 9533 and *Vancomycin*-Resistant *Enterococcus faecium* (VRE) ATCC 51559 and effectively kills canine Parvovirus with a 5-minute contact time.

ACCEPTED
with Comments
in EPA Letter dated
FEB 11 2008

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Description:

Use where control of the hazards of cross-contamination is of concern. Aids in the reduction of cross-contamination on treated surfaces. Opti-Cide 3 is particularly effective in: animal/pet care facilities, automobile interiors, barber shops, bathrooms, buses, cadaver processing areas, child care facilities (day care, infant care, schools), food processing facilities (non-food contact surfaces), funeral homes, health clubs, hotels, laboratories, long-term care facilities, medical facilities (ambulances/EMS/paramedic units, blood banks [centers], clean rooms, dental offices, drug preparation rooms, emergency rooms, hospitals, infant/child care units, isolation units [rooms] [areas], morgues, neonatal intensive care units, nursing homes, operating rooms, patient care areas, pharmacy surfaces, plasma pheresis centers, surgical centers), police vehicles, prisoner lockups, prisons, salons (beauty, manicure/pedicure, tanning, tattoo), skin care facilities, spas, train cars and other areas where the control of cross-contamination is important.

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When used as directed Opti-Cide 3 effectively cleans, decontaminates and disinfects hard, non-porous environmental surfaces such as: ambulance patient care surfaces, anesthesia equipment surfaces, animal cages (aviary, canine, feline, [REDACTED]), athletic/training facility surfaces, baby/infant care surfaces, backboards, bathing units, bed railings, blood pressure devices, brushes, cabinets, changing tables, combs, computer surfaces, countertops, CPR training devices, CT equipment/surfaces, curing lights, dental equipment surfaces/devices, diving equipment and air packs, doorknobs, food preparation surfaces, [REDACTED], firefighter turnout gear, floors, foot spa surfaces, gonial lenses, hair cutting/clipping implements, hair rollers, hard cervical collars/braces, helmets, hospitality and hotel surfaces, infant care equipment (bassinets, bed railings, cribs, incubators, tables, warmers, etc.), keyboards, laboratory equipment/surfaces, light lens covers, lumens, manicure/pedicure instruments and tables/chairs, mannequins, medical equipment surfaces/devices, microkeratome surfaces, microscopes, MRI equipment surfaces, neonatal/nursery surfaces, obstetrical equipment surfaces, operating room lights/tables, ophthalmic equipment surfaces/devices, optical wear (excluding contact lenses), oxygen hoods, patient bed surfaces, patient stretchers, patient transport surfaces, pet care surfaces, physical therapy equipment (such as bars, chairs, empty whirlpool tanks, etc.), play-care equipment, play mats, radiology equipment surfaces, refrigerators, respirators, respiratory care equipment surfaces, shampoo bowls, ship [river, ocean, sea vessel] surfaces, stalls, shower floors/walls, skin care equipment/surfaces, surgical equipment surfaces, surgical microscopes, tables, tanning bed surfaces, tattooing equipment surfaces/devices, telephones, toilets (rims, seats and [REDACTED] exterior surfaces), tonometer tips, toys, transportation equipment surfaces, [REDACTED] walls, wet/dry suits, work stations, wrestling mats, X-ray equipment/surfaces and [REDACTED] hard non-

exterior surfaces

(interior surfaces of ships)

OV ventilators

porous use sites listed on this label made of plastics (such as polycarbonate, polyvinylchloride, polypropylene and polystyrene), acrylic, non-porous vinyl, metal, stainless steel, painted, laminated and coated surfaces, Plexiglas® and glass.

Opti-Cide 3 is particularly effective for cleaning and disinfecting animal habitats, animal isolation units, animal laboratories, animal show facilities, animal/pet care facilities, aquariums, avian habitats, grooming facilities, reptile habitats, veterinary hospitals, zoo facilities and other similar animal care and house facilities where the chance of cross-contamination from infectious microorganisms is of concern. When used as directed, Opti-Cide 3 effectively cleans and disinfects hard, non-porous environmental surfaces such as: animal transport units (such as animal control vehicles and horse vans), bits, bowls, bridles, cages, clippers, examination tables, harness devices, incubators, instruments, kennels, litter boxes, pet care surfaces, sheers, troughs, veterinary equipment surfaces/devices, veterinary operating room lights and tables, warmers and ~~other~~ use sites including those made of plastics (such as polycarbonate, polyvinylchloride, polypropylene and polystyrene), acrylic, non-porous vinyl, metal, stainless steel, painted, laminated and coated surfaces, Plexiglas® and glass. For disinfection of Avian influenza A, use this product only for surfaces that are not conducive to treatment by immersion or excess liquid. exteno

Surfaces:

Cleaning: Prior to surface disinfection, clean surfaces by saturating surfaces with Opti-Cide 3 and allowing surfaces to remain wet for 15 seconds; then wipe clean using a fresh paper or cloth towel. Repeat, if necessary, until surfaces are visibly clean. Make sure surfaces are free of all gross filth and heavy soil. Discard paper towels or launder cloth towels before reusing. ~~Food preparation surfaces must be rinsed with potable water prior to use.~~

General Surface Cleaning:

Prior to surface disinfection, remove visible debris and gross filth such as animal excrement, visible blood or tissue and bedding materials such as blankets, litter, wood chips, hay or straw. Apply undiluted Opti-Cide 3 solution directly to surfaces by using a clean applicator such as a sponge, mop or cloth or spray directly onto soiled surface and allow surfaces to remain wet for approximately 15 seconds; then rinse and/or wipe surface until visibly clean and dry. Food preparation surfaces must be rinsed with potable water prior to use.

General [Bactericidal, Virucidal*, Fungicidal and Tuberculocidal] Disinfection: Reapply Opti-Cide 3 by sponge, mop, cloth, spray or dip to precleaned surfaces. Allow surface to remain wet for 3 minutes at room temperature (69°F/20°C) then wipe dry using a clean paper or cloth towel. Discard paper towels or launder cloth towels before reusing. [Food preparation surfaces must be rinsed with potable water prior to use.]

General Surface Disinfection:

Apply undiluted Opti-Cide 3 to precleaned surface by sponge, mop, cloth, or immersion or spray directly onto surface. Allow surface to remain visibly wet for 3 minutes (5 minutes for canine parvovirus); then wipe surface dry or allow to air dry; or rinse surface using potable water and either wipe surface dry or allow to air dry. [Food preparation surfaces must be rinsed with potable water prior to use.]

HCV, HBV and HIV-1 Precautions: Opti-Cide 3 effectively inactivates HCV, HBV and HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care 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 can be associated with the potential for transmission of HCV, HBV and HIV-1. **Special instructions for cleaning and decontamination against HCV, HBV and HIV-1 of surfaces/objects soiled with blood/body fluids:** **Personal Protection:** Wear appropriate barrier protection such as gloves, gowns, masks or eye coverings. **Cleaning**

Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces/objects before disinfection. **Contact Time:** Allow the surface to remain wet for 3 minutes prior to wiping. **Infectious Materials Disposal:** Cleaning materials used that may contain blood/body fluids should be autoclaved and/or disposed of in accordance with local regulations for infectious materials disposal.

This product is not to be used as a terminal sterilant or 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 sterile areas of the body. This product may be used to pre-clean or decontaminate critical and semi-critical medical devices prior to sterilization or high-level disinfection.

Instruments:

For Use as a Pre-Cleaning Instrument Decontamination Soak Solution: Fill appropriately sized container with a sufficient amount of undiluted Opti-Cide 3 to allow for complete submersion of instruments/devices. Place instruments/devices into solution and allow to soak at room temperature (69°F/20°C) for 3 minutes, then remove instruments/devices and rinse. Follow with the appropriate cleaning and disinfection or sterilization process. Change solution as needed, i.e., when the solution becomes diluted or visibly soiled.

For Use as a Pre-Cleaning Instrument Decontamination Spray: Place instruments into suitable container. Thoroughly spray instrument surfaces with undiluted Opti-Cide 3 to thoroughly drench surfaces. Allow instruments to remain wet for 3 minutes, thoroughly rinse, then follow with the appropriate terminal cleaning and sterilization/disinfection process.

For Use as an Ultrasonic Decontamination Cleaning Solution: Place instruments/devices into the Opti-Cide 3 pre-filled ultrasonic unit. Activate unit to operate for 3 minutes. When unit shuts off, remove instruments/devices and thoroughly rinse. For critical and semi-critical instruments/devices follow decontamination with an appropriate sterilization or high-level disinfection process as required.

For Use as an Ultrasonic Cleaning Solution:

Place instruments/devices into an Opti-Cide 3 pre-filled ultrasonic unit. Activate unit to operate for 3 minutes. When unit shuts off, remove instruments/devices and thoroughly rinse, then dry or allow to air dry.

For Cleaning [To Clean] Hair Clippers and Electric Shears: Disconnect the clipper/shear from the electrical supply. Hold it in the downward position and spray Opti-Cide 3 directly onto the blades making sure the solution does not drain into the housing. Allow to remain wet for 15 seconds and wipe dry with a clean, soft cloth. Lubricate the blades per manufacturer's instructions.

For Use as an Instrument/Device Disinfection Solution: Clean instruments/devices to remove organic soil then rinse and rough dry. Flush lumens of hollow instruments/devices before filling with solution or immersion. Immerse instruments/devices into undiluted Opti-Cide 3 solution and allow to soak for 3 minutes at room temperature (69°F/20°C). Remove and rinse or wipe instruments/devices dry.

Disinfection of Instruments, Implements and Devices:

Spray directly on visibly clean instruments, implements or devices. Allow to remain wet for 3 minutes 5 minutes for canine parvovirus; then before use wipe surface dry or allow to air dry. Rinse surface using potable water and either wipe surface dry or allow to air dry.

ACCEPTED
with comments
in EPA Label Draft

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Disinfection Immersion Solution:

Clean instruments/devices to remove organic soil and gross filth, then rinse and rough dry. Flush lumens of hollow instruments/devices before filling with solution or immersion. Immerse instruments/device into undiluted Opti-Cide 3 solution, fill lumens and allow to soak for 3 minutes (5 minutes for canine parvovirus) at 69°F/20°C. Remove and rinse exterior and inside of lumens to remove solution then wipe instruments/devices dry or allow to air dry.

Storage and Disposal

Do not contaminate food or feed by storage or disposal.

Storage: Store in a cool, well-ventilated area. **Product Disposal:** Unused product may be discarded by pouring down the drain and flushing drain with water. **Container Disposal:** Triple rinse empty container, 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, dispose of by burning. If burned, stay out of smoke.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if inhaled or absorbed through skin. Causes moderate eye irritation. Avoid breathing vapors and contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

First Aid

If Inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.
If in Eyes	<ul style="list-style-type: none">• 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 eye.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-255-3924 for emergency medical treatment information.

{The First Aid statements' grid format will be used if market label space permits; otherwise a paragraph format will be used.}

Physical or Chemical Hazards

Do not use or store near heat or open flame.

Manufactured in the U.S. A. for:
Micro-Scientific Industries, Inc.

[Corporate Offices:] 1225 Carnegie Street; Rolling Meadows, IL 60008 U.S.A.

Telephone: 1-888-253-2536

www.opticide.com

Order No: _____

[] Denotes alternate language

{ } Denotes language that does not appear on the market label

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

FEB 11 2008

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