

70144-1

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

FEB 5 2009

Ms. Kim Davis  
Consultant for Micro-Scientific Industries, Inc  
30856 Rocky Road  
Greely, CO 80631-9375

Subject: Opti-Cide 3  
EPA Registration No.: 70144-1  
Amendment Date: November 6, 2008  
EPA Receipt Date: November 7, 2008

Dear Ms. Davis,

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

- Deletion of *Clostridium difficile* (vegetative)

**Conditions**

Revise the label as follows:

- 1) Revise the 3<sup>rd</sup>, 4<sup>th</sup>, and 5<sup>th</sup> claims on page one by deleting the term, decontamination because this product is not a liquid chemical sterilant. The term, decontamination, has been associated with liquid chemical sterilants implying that the product mitigates all forms and species of microorganisms.
- 2) Revise the 13<sup>th</sup> claim on page one by deleting the term, biodegradable because it is an implied safety claim that is false and misleading (40 CFR 156.10 (a)(5)I).
- 3) Revise the 16<sup>th</sup> claim on page one by deleting the phrase, "For Professional Use" because it is considered false and misleading since the product is not classified as a restricted use pesticide.
- 4) Delete the term, decontaminate, from the second paragraph, first statement on page 2.
- 5) Revise the first statement in the first paragraph on page 3 by deleting the term, infectious, and stating "Opti-Cide 3 is particularly effective against ~~infectious~~ contamination from microorganisms is of

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### **Animal Housing/Veterinary Hospitals/Animal Laboratory Disinfection Directions:**

**Surgical Instrument Presoak:** Fill container with Opti-Cide 3 to allow for complete submersion of instruments/devices. Place pre-cleaned instruments in solutions for a minimum of 3 minutes (5 minutes for Canine parvovirus), then proceed with normal sterilization process. Prepare a fresh solution at least daily or when solution becomes visibly dirty or discolored.

**CONCURRENCES**

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YMBOL	objects compatible with Ultrasonic cleaning units. 150 psi. Cide 3 into bath chamber. Place pre-
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cleaned objects into unit and operate for a minimum of 3 minutes (5 minutes for Canine parvovirus) according to manufacturer's use directions. Remove objects and rinse with sterile water or allow to air dry. Prepare a fresh solution at least daily or when solution becomes visibly dirty or discolored.

**Barber and Beauty Salon Instrument Disinfection Directions:** Immerse pre-cleaned barber/salon tools (combs, brushes, razors, manicure/pedicure tools, clippers, trimmer blades, tweezers, and scissors in Opti-Cide 3 solution. Allow objects to remain wet for 3 minutes. Rinse thoroughly and dry before use. Prepare a fresh solution at least daily or when solution becomes visibly dirty or discolored.

**Disinfect Hair Clippers and Electric Shears:** Disconnect the clippers/shears from the electrical outlet. Hold clippers/shears in downward position and spray Opti-Cide 3 onto the blades two or three times to thoroughly wet blades. Do not spray directly into housing. Allow blades to remain wet for 3 minutes. Then wipe dry with clean cloth. Lubricate as per clipper/shear manufacturer's instructions.

13) Revise the "Storage and Disposal" statements"

(Containers equal to or less than 1 gallon)

**Storage and Disposal**

Store in a cool, well ventilated area in accessible to children and persons unfamiliar with its use. Do not reuse or refill container. Wrap container in trash or offer for recycling if available.

(Containers greater than 1 gallon)

**Storage and Disposal**

Do not contaminate food or feed by storage or disposal

**Pesticide Storage:** Store in a cool, well ventilated area in accessible to children and persons unfamiliar with its use

**Pesticide Disposal:** Waste resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**Container Disposal:** Do not reuse or refill container. Triple rinse empty container, then offer for recycling or reconditioning, or dispose of in a sanitary landfill. If allowed by state and local authorities, dispose by burning. If burned stay out of smoke.

**General Comments**

A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label 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) 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(c)(1). Full release for shipment of the product

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bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233 or Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

Enclosures: Stamped Label  
Efficacy Data Evaluation

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## 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 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<sub>14</sub>, 30% C<sub>16</sub>, 5% C<sub>12</sub>, 5% C<sub>18</sub>)

dimethyl benzyl ammonium chloride

n-Alkyl (68% C<sub>12</sub>, 32% C<sub>14</sub>) dimethyl ethylbenzyl

ammonium chloride

### Other Ingredients

Total

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

FEB 5 2009

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

100-0000 70144-1

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.

{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, *Chlamydomonas psittaci* ATCC VR-125, *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

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**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, *Chlamydomphila psittaci* ATCC VR-125, 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.**

### 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 areas where the control of cross-contamination is important.

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), 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, 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 [exterior surface]), 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), play-care equipment, play mats, radiology equipment surfaces, refrigerators (exterior surface), respirators, respiratory care equipment surfaces, shampoo bowls, interior 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 exterior surfaces), tonometer tips, toys, transportation equipment surfaces, walls, wet/dry suits, work stations, wrestling mats, X-ray equipment/surfaces and hard non-porous use sites listed on this label made of

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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 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 (exterior surface) and 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.

#### **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.

#### **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.

**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.

#### **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.

**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 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/or the human immunodeficiency virus Type 1 (HIV-1) associated with AIDS. **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 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; or rinse surface using potable water and either wipe surface dry or allow to air dry.

**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



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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

<b>If Inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> </ul>
<b>If on Skin or Clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>
<b>If in Eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
<p>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.</p>	

{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