



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

DEC 19 2006

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Ms. Kim Davis  
Regwest Company  
Micro-Scientific Industries, Inc.  
30856 Rocky Road  
Greeley, CO 80631-9375

Subject: Opti-Cide 3

EPA Registration Number 70144-1

Your Amendment(s) Dated July 27<sup>th</sup>, 2006 and August 24<sup>th</sup>, 2006

EPA Received Date(s) August 9<sup>th</sup>, 2006 and August 31<sup>st</sup>, 2006

The amendment(s) referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to additional organisms, *Acinetobacter Baumannii*, Rotavirus Strain WA, Avian Influenza A(H3N2) virus, *Bordetella Bronchiseptica*, and Infectious Bovine Rhinotracheitis virus to the product labeling, is acceptable.

The submitted efficacy data (MRID No. 469028-01) support the use of the product, Opti-Cide 3 Disinfectant Cleaner, as a disinfectant with bacterial activity against *Acinetobacter baumannii* and *Bordetella bronchiseptica* on hard, non-porous surfaces for a contact time of 3 minutes at full strength, in absence of soil.

The submitted efficacy data (MRID No. 469028-02) support the use of the product, Opti-Cide 3 Disinfectant Cleaner, as a disinfectant with virucidal activity against Rotavirus, Avian Influenza A (H3N2), and Infectious bovine rhinotracheitis virus on hard, non-porous surfaces in the presence of a 1% organic soil load for a contact time of 3 minutes at full strength.

The proposed label claims that the product, Opti-Cide 3, is an effective disinfectant against *Acinetobacter baumannii*, *Bordetella bronchiseptica*, Rotavirus, Avian Influenza A virus, and Infectious bovine rhinotracheitis virus on pre-cleaned, hard, non-porous surfaces for a contact time of 3 minutes at full strength. Data provided support these claims.

Please note: the ATCC website lists organisms as *Acinetobacter baumannii* (with two letter "n's" in the word "baumannii").

Hospital disinfection directions are not present on the proposed label. Either provide a separate section for these directions, or expand the general disinfection direction section to include hospital disinfection directions.

For Avian Influenza A claims, it should be made clear that the product's use is only for surfaces which are not conducive to treatment by immersion or excess liquid (e.g., cages, equipment tables, lab benches, faucet handles, door knobs, and similar "high touch" surfaces). For uses in hospital/medical/health facilities, the directions for use for hospital Disinfection should be used.

If the product is marketed in larger packaging sizes (e.g.,  $\geq 55$  gallons) for use on poultry premises, as shown on page 2 of the proposed label, the following label directions are required to permit their classification as non-food products:

- (a) Remove all poultry and feeds from premises, trucks, coops, and crates.
- (b) Remove all litter droppings from floors, walls, and surfaces of facilities occupied or traversed by poultry.
- (c) Empty all troughs, racks, and other feeding and watering appliances
- (d) Thoroughly clean all surfaces with soap and detergent rinse with water
- (e) Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes
- (f) Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried
- (g) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Current packaging sizes and site/pest relationships do not warrant the directions listed for farm and poultry premises.

Featured statements/phrases emphasized/enlarged lettering, special graphics, or any product name that employs the terms "Avian Influenza A" or "Bird Flu", are unacceptable. Featured statements/phrases, emphasized/enlarged lettering or special graphics that are employed for the primary purpose of especially promoting or drawing attention to product efficacy against Avian Influenza A, are also unacceptable. For example, a featured, incomplete phrase such as "Kills Avian A" will not be permitted, but the phrase "Kills Avian Influenza A on pre-cleaned environmental surfaces" is acceptable.

Isopropanol is listed as an active ingredient for Opti-Cide 3. The percentage of isopropanol used in the formulation was 21.00%. At this percentage, antimicrobial properties are not exhibited. Please remove isopropanol from the list of active ingredients.

Revise the product labeling to read as follows:

Revise the phrase, "Clostridium difficile" to read "Clostridium difficile (vegetative)

Revise the phrase, "Multi-Drug Resistant Staphylococcus aureus" to read "Methicillin-Drug Resistant Staphylococcus aureus".

Inactivated (kill) time ("While the HIV virus is inactivated in 30 seconds...") and contact time are analogous terms. Please remove the shorter time of 30 seconds, as this is consistent with the contact time of 3 minutes.

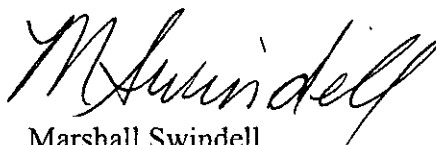
The designation "Salmonella choleraesuis" has been changed to "Salmonella enterica" effective immediately. This change should be reflected on the current and future submissions. <http://www.atcc.com/common/catalog/numResults.cfm?atccNum=10708>.

Include HCV and HBV in the special instructions for HIV. Since both HCV and HBV are bloodborne pathogens, special instructions are required for disinfection and disposal of contaminated areas.

A stamped copy of the labeling is enclosed for records.

If you have any questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobial Division (7510C)

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# Opti-Cide® 3

Barber/Salon [Clipper Blade] Disinfectant/Cleaner

Veterinary/Animal Care Facility Disinfectant/Cleaner

Disinfectant/Decontamination Cleaner

Surface Disinfectant/Decontamination Cleaner

Medical/Surgical/Dental Equipment Disinfectant Cleaner and Decontaminant

Bactericidal • Fungicidal • Virucidal\* • Tuberculocidal

Ready-to-Use

[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 ..... 0.154%

n-Alkyl (68% C<sub>12</sub>, 32% C<sub>14</sub>) dimethyl ethylbenzyl  
ammonium chloride ..... 0.154%

Isopropanol ..... 21.000%

Other Ingredients ..... 78.692%

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.

{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* ATCC 9689, *Staphylococcus aureus* ATCC 6538, *Pseudomonas aeruginosa* ATCC 15442, *Salmonella choleraesuis* ATCC 10708, Multi-Drug Resistant *Staphylococcus aureus* (MRSA) ATCC 33591 and *Enterococcus faecium* (VRE) ATCC 51559.

**[Pathogenic Fungi:]** *Trichophyton mentagrophytes* ATCC 9533

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

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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, *Clostridium difficile* 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 choleraesuis* ATCC 10708, *Staphylococcus aureus* ATCC 6538, Multi-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.**

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### DIRECTIONS FOR USE

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

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

#### 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: medical facilities (ambulances/EMS/paramedic units, dental offices, emergency rooms, hospitals, plasma pheresis centers, blood banks, infant/child care units, isolation units, neonatal intensive care units, operating rooms, patient care areas, surgical centers), [animal care facilities,] cadaver processing areas, funeral homes, morgues, food processing facilities (non-food contact surfaces), health clubs, bathrooms, laboratories, police vehicles, prisoner lockups, prisons, barber shops, salons (beauty, manicure/pedicure, tanning, tattoo), spas, child care facilities (infant care, day care, schools) and other 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, CPR training devices, mannequins, tonometer tips, backboards, bathing units, blood pressure devices, curing lights, dental equipment surfaces/devices, gonial lenses, hard cervical collars/braces, infant care equipment (bassinets, bed railings, incubators, tables, warmers, etc.), laboratory equipment/surfaces, light lens covers, medical equipment surfaces/devices, operating room lights/tables, ophthalmic equipment surfaces/devices, oxygen hoods, patient stretchers, physical therapy equipment (such as chairs, bars, empty whirlpool tanks, etc.), [animal cages (aviary, canine, feline, etc.),] bed railings, cabinets, countertops, doorknobs, helmets, shower floors/walls, tables, toilets (seats, rims and other exterior surfaces), work stations, wrestling mats, optical wear (excluding contact lenses), firefighter turnout gear, diving equipment and air packs, wet/dry suits, brushes, combs, hair cutting/clipping implements, hair rollers, manicure/pedicure instruments and tables/chairs, shampoo bowls, tanning bed surfaces and other hard non-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.

Opt-Cide 3 is particularly effective for cleaning and disinfecting animal care facilities and animal habitats, veterinary hospitals, animal isolation units, animal laboratories, animal show facilities, grooming facilities, zoo facilities, aquariums, reptile habitats 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: avian habitats, kennels, cages, animal transport units (such as horse vans and animal control vehicles), litter boxes, examination tables, veterinary equipment surfaces/devices, incubators,

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warmers, veterinary operating room lights and tables, clippers, sheers, bowls, troughs, instruments, bits, bridles, harness devices 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.

#### 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; 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.

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**HIV-1 Precautions:** Opti-Cide 3 effectively inactivates 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 the human immunodeficiency virus Type 1 (HIV-1) associated with AIDS. **Special instructions for cleaning and decontamination against 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:** While the HIV-1 virus is inactivated in 30 seconds, 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

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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; 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 instruments/device into undiluted Opti-Cide 3 solution, fill lumens and allow to soak for 3 minutes 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.

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## 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>

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

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