
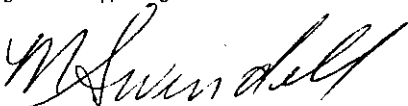


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|--|---|--|---|
|  | U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Antimicrobials Division (7510C) 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460 | EPA Reg. Number: 70144-1 | Date of Issuance: NOV 24 2004 |
| | | Term of Issuance: CONDITIONAL Expires on May 1, 2005 | |
| | | Name of Pesticide Product: Opti-Cide 2 | |
| Name and Address of Registrant (include ZIP code): Micro-Scientific Industries, Inc. 1225 Carnegie Street, Suite 104B Rolling Meadows, IL 60008 | | | |
| Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number. | | | |
| On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is conditionally registered in accordance with FIFRA Section 3(c)(7)(A) provided that you: 1. Submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA Section 4, or as required by registration review under FIFRA Section 3(g). 2. Make the following labeling changes: a. Revise the EPA Registration Number to read, "EPA Reg. No. 70144-1." b. Place the appropriate EPA Establishment No. on the product labeling. | | | |
| Signature of Approving Official:  Marshall Swindell, Product Manager, Team 33, Regulatory Management Branch I, Antimicrobials Division | | Date: NOV 24 2004 | |

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EPA Reg. No.70144-1

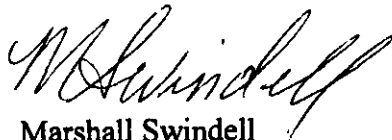
3. Submit five (5) copies of your final printed labeling before you release the product for shipment.
4. The Agency is extending your conditional registration for this product until **May 1st, 2005**, to allow you to conduct a full set of efficacy data for all of the claims on your product label. This data is to be conducted in accordance with the appropriate DIS/TSS Enclosure for each organism on the label. Submit your newly completed bacterial data by May 15th, 2004. Submit all other fungicidal, virucidal, and tuberculocidal data to the Agency by November 30th, 2004. If your bacterial data is found to be unacceptable the Agency will immediately stamp a label bearing efficacy claims identical to those of your source product's data to support your registration. If your fungicidal, virucidal, or tuberculocidal data is found to be unacceptable each unsupported claim will be deleted from the label immediately in accordance with your April 21st, 2004 written agreement.

A stamped copy of the labeling is enclosed for your records.

If these 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 constitutes acceptance of these conditions.

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

Sincerely,



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

Enclosure

3/5

Opti-Cide® 2

Barber/Salon [Clipper Blade] Disinfectant/Cleaner

Veterinary 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 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 benzyl | |
| ammonium chloride | 0.154% |
| Isopropanol | 21.000% |
| Other Ingredients | 78.692% |
| Total | 100.000% |

Keep Out of Reach of Children

CAUTION

See back panel for additional precautionary statements.

EPA Reg. No. 70144-R 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:

NOV 24 2004

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

70144-1

{Back Panel}

Opti-Cide 2 effectively kills the following microorganisms at room temperature (60°F/20°C) with a 30-seconds contact time:

***Viruses:** Herpes Simplex II Virus (HSV 2) G Strain, Human Immunodeficiency Virus (HIV-1) (associated with AIDS) and Influenza Virus Strain A2/Hong Kong

Opti-Cide 2 effectively kills the following microorganisms at room temperature (60°F/20°C) with a 3-minutes contact time:

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

***Viruses:** Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Polio I Virus ATCC VR-58 and Rhinovirus ATCC VR-286

Gram Positive and Gram Negative Bacteria: *Staphylococcus aureus* ATCC 6538, *Pseudomonas aeruginosa* ATCC 15442 and *Salmonella choleraesuis* ATCC 10708

Pathogenic Fungi: *Trichophyton mentagrophytes* ATCC 9533

NOV 24 2004

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

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 2 is particularly effective in: medical facilities (ambulances/EMS/paramedic units, dental offices, emergency rooms, hospitals, plasma phoresis 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 2 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, mats, 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 environmental surfaces including those made of plastics (such as polycarbonate, polyvinylchloride, polypropylene and polystyrene), vinyl, stainless steel, painted surfaces, Plexiglas® and glass.

Cleaning: Prior to surface disinfection, clean surfaces by saturating surfaces with Opti-Cide 2 and allowing surfaces to remain wet for 30 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 [Bactericidal, Virucidal*, Fungicidal and Tuberculocidal] Disinfection:** Reapply Opti-Cide 2 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.

HIV-1 Precautions: Opti-Cide 2 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.

For Use as a Pre-Cleaning Instrument Decontamination Soak Solution: Fill appropriately sized container with a sufficient amount of undiluted Opti-Cide 2 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 2 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 2 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 Cleaning Hair Clippers and Electric Shears: Disconnect the clipper/shear from the electrical supply. Hold it in the downward position and spray Opti-Cide 2 directly onto the blades making sure the solution does not drain into the housing. Allow to remain wet for 30 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 2 solution and allow to soak for 3 minutes at room temperature (69°F/20°C). Remove and rinse or wipe instruments/devices 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 unless market label space is sufficient; 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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 24 2004

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

[] Denotes alternate language

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

70144-1