

70144-1

10-29-2003
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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OCT 29 2003

Micro-Scientific Industries, Inc.
1225 Carnegie Street
Rolling Meadow, IL 60008

AGENT: REGWEST COMPANY
3056 Rocky Road
Greeley, CO 80631-9375

Attention: Kim Davis, CC, APC, Manager
Consultant/Agent

Subject: Opti-Cide 2
EPA Registration No. 70144-1
Amendment Dated September 15, 2003

This will acknowledge receipt of your notification for the following additional brand name, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

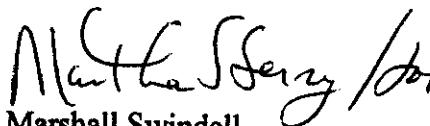
Additional Brand Name

Opti-Cide 3

The notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely



Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1

CONCURRENTLY Antimicrobials Division (7510C)

SYMBOL								
SURNAME								
DATE								

United States Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, DC 20460-0001	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide – Section I

1. Company/Product Number EPA Reg. No. 70144-1	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/ Product (Name) Opti-Cide 2	PM # 33	
5. Name and Address of Applicant (Include ZIP Code) Micro-Scientific Industries, Inc. c/o RegWest Company, LLC 30856 Rocky Road Greeley, CO 80631-9375	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i) my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address		

Section – II

<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated 07/22/03 <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.
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Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

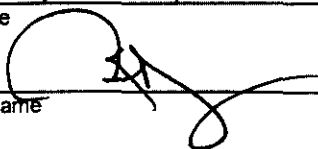
**Submit additional brand name and label revision notification per PR Notice 98-10.
The additional brand name is: Opti-Cide-3**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR § 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR § 152.46 this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
*Certification must be submitted	If "Yes" Unit Packaging Wgt.	No. Per Container	If "Yes" Packaging Wgt.	No. Per Container	<input type="checkbox"/> Other (Specify): _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 8 ounces through 2½ gallons		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling Accompanying Product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Stenciled <input type="checkbox"/> Paper glued <input type="checkbox"/> Other _____					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).		
Name Kim Davis, CC, APC, Manager	Title Consultant/Agent	Telephone No. (Include Area Code) (970) 353-0611
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Consultant/Agent	
4. Typed Name Kim Davis, CC, APC, Manager	5. Date September 15, 2003	

Medical / Surgical / Dental Equipment
Disinfectant Cleaner & Decontaminant

Bactericidal • Fungicidal • Virucidal[®] • Tuberculocidal[®]

Opti-Cide³®

For Professional Use • Ready to Use

ACTIVE INGREDIENTS:

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride.....0.154%

n-Alkyl (68% C12, 32% C14) 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 panel for additional precautionary statements

Manufactured for:



Made in the U.S.A.

Net Contents: 1 U.S. Gallon / 3.785 Liters

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	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	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
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 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.	

Physical or Chemical Hazards

Do not use or store near heat or open flame.

EPA REG. NO. 70144-1

EPA EST. 1130-IL-1

ORDER NO: OCP04-128

Manufactured for:
Micro-Scientific Industries, Inc.
1225 Carnegie Street
Rolling Meadows, IL 60008 USA
Telephone: 1-800-253-2536
www.opticide.com



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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.

Opti-Cide-3 effectively kills the following microorganisms at room temperature (60°F/20°C) with a 30 second contact time: * Herpes Simplex II Virus (HSV 2) G Strain, *Human Immunodeficiency Virus (HIV-1) (associated with AIDS) and *Influenza Virus Strain A2/Hong Kong, and effectively kills the following microorganisms at room temperature (60°F/20°C) with a 3 minute contact time: ***Mycobacterium bovis* BCG (tuberculosis) (TB), *Staphylococcus aureus* ATCC 6538, *Pseudomonas aeruginosa* ATCC 15442, *Salmonella choleraesuis* ATCC 10708, *Trichophyton mentagrophytes* ATCC 9533, * Hepatitis B Virus (HBV), *Hepatitis C Virus (HCV), * Rhinovirus ATCC VR-286 and *Polio I Virus ATCC VR-58.

Description: Use where control of the hazards of cross-contamination is of concern. Opti-Cide-3 is particularly effective in: medical facilities, hospitals, surgical centers, isolation units, neonatal intensive care units, EMS/paramedic units, plasma phoresis centers, laboratories, dental offices, operating rooms, emergency rooms, morgues 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: medical equipment surfaces/devices, ophthalmic equipment surfaces/devices, dental equipment surfaces/devices, anesthesia equipment surfaces, infant care equipment (bassinet, incubators, warmers), laboratory equipment/surfaces, operating room lights/tables, oxygen hoods, physical therapy equipment (such as empty whirlpool tanks), gonial lenses, tonometer tips and other hard non-porous environmental surfaces including those made of plastic, (such as: polycarbonate, polyvinyl chloride, polypropylene and polystyrene), vinyl, stainless steel, painted surfaces, Plexiglas and glass.

HIV-1 Precautions: Opti-Cide-3 effectively inactivates HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare 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.

SURFACES:

Cleaning: Prior to surface disinfection, clean surfaces by saturating surfaces with Opti-Cide-3 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 Disinfection: Re-apply Opti-Cide-3 by sponge, cloth or spray to pre-cleaned 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 towel before reusing.

INSTRUMENTS:

For Use as 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 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 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 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. Remove and rinse or wipe instruments/devices dry.

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.

STORAGE AND DISPOSAL

Do not contaminate food or feed by storage or disposal. **Storage:** Store in 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.