

70144-2

08/08/2007

119



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

OFFICE OF
PREVENTION PESTICIDES AND
TOXIC SUBSTANCES

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

AUG 8 2007

Attention: Kim Davis
Regulatory Manager

Subject: Notification for Additional Brand Name
Opti-Cide 3 Wipes ®
EPA Registration No. 70144-2
Amendment Letter dated June 8, 2007

This will acknowledge receipt of your notification for the aforementioned product label, submitted under the provisions of FIFRA Section 3(c) (9). Based on a review of the submitted material, the following apply:

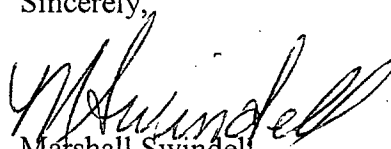
- The addition of alternate brand names Opti-Cide 3 Surface Wipes and Opti-Cide 3 V Surface Wipes
- Additional Use Sites
- Clarifying the Contact time for the Canine Parvovirus
- Additional clarification with use directions/intstructions

The Notification is in compliance with PR Notice 98-10 and is acceptable with some comments. Some of the use sites/statements listed in the label are not appropriate. The following language in the Direction for Use section must be removed or clarified:

- Spot Cleaning – The language is ambiguous and needs to be clarified as to what surfaces in animal care facilities are to be spot cleaned.

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

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell", written over the printed name.

Marshall Swindell

Product Manager (33)

Regulatory Management Branch 1

Antimicrobials Division (7510C)

3 | 9

June 8, 2007



Mr. Marshall Swindell, Product Manager 33
Document Processing Desk – **NOTIF**
Office of Pesticide Programs – **7504C**
U.S. Environmental Protection Agency
2777 South Crystal Drive
One Potomac Yard, Room S-4900
Arlington, VA 22202

Dear Mr. Swindell:

Subject: Micro-Scientific Industries, Inc.
Opti-Cide-3 Wipes
EPA Reg. No. 70144-2

On behalf of **Micro-Scientific Industries, Inc.**, RegWest Company, LLC is submitting the attached materials as notification of a label revision and additional brand names and to submit final printed labeling per the EPA letter of April 11, 2007. RegWest will act as sole agent in this endeavor.

Attached are the following documents:

1. Application for Pesticide: Other (Notification)
2. One **Reference Label** (illustrating the revisions)
3. Two **New Labels** (incorporating the revisions)
4. Final printed labels (for the additional brand name products)

The additional brand names are:

Opti-Cide 3 Surface Wipes
Opti-Cide 3 V Surface Wipes

Please refer to the **Reference Label** for an illustration of the label revisions. We are primarily adding marketing copy to the front panel, some use sites related to those already approved and clarifying in the use directions that there is a 5-minute contact time for Canine Parvovirus.

Please contact me at (970) 353-0611 or at kim@regwest.com if you have any questions or require additional information.

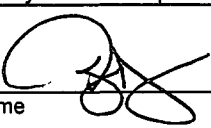
Regards,
RegWest Company, LLC

Kim Davis, CC, APC, Manager
Consultant/Agent

Attachments

pc: MSI – Wager, J.

30856 Rocky Road
Greeley, CO 80631-9375
970-353-0611
970-353-0613 Fax
Kim@regwest.com

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 <div style="border: 1px solid black; padding: 5px; text-align: center; font-weight: bold;">Notification</div>
Application for Pesticide – Section I			
1. Company/Product Number EPA Reg. No. 70144-2		2. EPA Product Manager Marshall Swindell	
4. Company/ Product (Name) Opti-Cide-3 Wipes		3. Proposed Classification PM # 33 <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
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 <input type="checkbox"/> Check if this is a new address		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 _____	
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 04/11/2007 <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Submit additional brand names and label revision notification per PR Notice 98-10. (Refer to the Reference Label for an illustration of label revisions) Submit final printed labeling in response to the EPA letter dated April 11, 2007. The additional brand names are: Opti-Cide 3 Surface Wipes and Opti-Cide 3 V Surface Wipes <i>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.</i>			
Section – III			
1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify): _____
*Certification must be submitted		If "Yes" Unit Packaging Wgt. No. Per Container	If "Yes" Packaging Wgt. No. Per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
		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 kim@regwest.com	
Certification			6. Date Application Received <div style="border: 1px solid black; padding: 10px; font-weight: bold;">(Stamped)</div>
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.			
2. Signature 		3. Title Consultant/Agent	
4. Typed Name Kim Davis, CC, APC, Manager		5. Date June 8, 2007	

5/9

Opti-Cide®-3 Wipes

Disinfectant/Cleaner

Veterinary/Animal/Pet Care Facility Disinfectant/Cleaner

Medical/Surgical/Dental Equipment Disinfectant Cleaner and Decontaminant

Surface Disinfectant/Decontamination Cleaner

Bactericidal • Fungicidal • Virucidal

Disinfectant Cleaner [and] Deodorizer

Disinfects Cleans Deodorizes

Kills Bacteria - Viruses - Fungus on hard, non-porous surfaces such as {select from use directions}
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

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%

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. 70144-2 EPA Est. 1130-IL-1

Net Contents: _____ wipes

Net Weight: _____ oz. (_____ g)

Product Order Number: _____

{flag graphic}

Made in the U.S.A.

{Back/Side Panel(s)}

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

- *Acinetobacter baumannii* (ATCC 19606)
- 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

6/9

- Canine Para-Influenza Virus ATCC VR-666
 - *Clostridium difficile* (vegetative) ATCC 9689
 - Duck Hepatitis B Virus (DHBV – Surrogate Hepatitis B Virus)
 - *Enterococcus faecium* (VRE) ATCC 51559
 - Feline Leukemia Virus
 - Hepatitis B Virus (HBV)
 - Hepatitis C Virus (HCV)
 - Herpes Simplex II Virus (HSV 2) G Strain
 - Human Immunodeficiency Virus (HIV-1) (associated with AIDS)
 - Infectious Bovine *Rhinotracheitis* Virus ATCC VR-188
 - Influenza Virus Strain A2/Hong Kong
 - Multi-Drug Resistant *Staphylococcus aureus* (MRSA) ATCC 33591
 - Polio I Virus ATCC VR-58
 - *Pseudomonas aeruginosa* ATCC 15442
 - Rhinovirus ATCC VR-286
 - Rotavirus Strain WA
 - *Salmonella enterica* ATCC 10708
 - *Staphylococcus aureus* ATCC 6538
 - *Streptococcus equi* ATCC 33398
 - *Trichophyton mentagrophytes* (ringworm) ATCC 9533
 - Vancomycin-Resistant *Enterococcus faecium* (VRE) ATCC 51559
- and effectively kills with a 5-minute contact time at room temperature (69°F/20°C)
- Canine Parvovirus

DIRECTIONS FOR USE

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

Do not use this product as a baby or skin wipe, or on contact lenses!

Opti-Cide-3 Wipes are disposable, single-use towelette wipes pre-saturated with Opti-Cide-3 disinfectant solution. Opti-Cide-3 Wipes are intended for use on hard, non-porous inanimate surfaces in areas where the disinfection of surfaces is required.

When used as directed Opti-Cide-3 Wipes clean and disinfect surfaces found in animal transport vehicles, animal/pet care facilities, animal/pet housing facilities, animal labs, athletic clubs, autopsy rooms, bathrooms, blood centers, cadaver work areas, cardiac care labs, cardiac catheterization labs, cardiology units, central sterile supply, central supply areas, child care facilities, clean rooms, clinical areas, daycare centers, dental facilities, dialysis units, drug preparation facilities, EMS units, endoscopic rooms, equine facilities, esthetician facilities, extended care facilities, field hospitals, funeral homes, GI laboratories, gyms, hair salons, hospitals, hotels, human transport vehicles, infant care units, institutional facilities, intensive care units, isolation rooms [units], laboratories, large animal care facilities, lasik centers, locker rooms, long-term care facilities, medical offices, morgues, nail care facilities, nail salons, neonatal units, newborn nurseries, nursing homes, offices, operating rooms, ophthalmic centers, paramedic squads, pathology facilities, pheresis equipment and centers, podiatry offices, prisoner holding areas, radiology centers, research laboratories, respiratory care units, salons, schools, skin care facilities, small animal care facilities, surgical centers and rooms, trailers, transport equipment, veterinary facilities, veterinary hospitals, workout rooms, zoologic centers, zoos and other areas/facilities concerned with the hazards of cross-contamination from infectious microorganisms.

Opti-Cide-3 Wipes may be used on ambulance equipment and surfaces, anesthesia equipment surfaces, animal cages (aviary, canine, feline, etc.), animal examination tables, animal habitats, athletic/training facility surfaces, baby/infant care surfaces, back boards, bassinets, bed rails, beds, breathing masks, cages, canine care surfaces, commodes, computer keyboards, counters, dialysis machine surfaces, door knobs, EMS equipment/work surfaces, endoscopic devices, equine care surfaces, equipment surfaces, ER surfaces, examination tables, eye glasses, eye protection devices, feline care surfaces, finished surfaces, foot spas, funeral home surfaces, goggles, helmets, hospitality and hotel surfaces, incubators, infant warmers, instrument stands, Isolettes®, kennel cages, kennels, kidney machines, laminated surfaces, large animal care surfaces, litter boxes, loupes, mats, mayo stands, monitor knobs, monitors, morgue tables, neonatal/nursery surfaces, non-critical devices, nursing station surfaces, OB surfaces, occupational therapy devices, office fixtures, OR lights, OR surfaces, OR tables, oxygen hoods, oxygen tents, painted surfaces, patient care devices, patient care equipment surfaces, patient examination tables, pet care surfaces, pharmacy surfaces, physical therapy equipment, pulmonary function equipment, pumps, rails, reptile care surfaces, respiratory therapy equipment, showers, sink faucets, sinks, small animal care surfaces, spirometers, stair chairs, stretchers, tanks, telephones, toilets, toys, transport van surfaces, turn-out gear, ventilators, warmers, wheel chairs, whirlpool surfaces, x-ray equipment surfaces and other devices/surfaces potentially contaminated with disease-causing microorganisms [and other use sites made of glass, metal, Plexiglas®, plastics (i.e., polycarbonate, polypropylene, polyvinylchloride and polystyrene), baked-on painted surfaces, stainless steel and non-porous vinyl.]

{For canister dispensing:}

Dispensing Directions:

To start feed, remove cover and discard seal. From the center of the wipe roll, pull up a wipe corner, twist it into a point and thread it through the hole located on the container cover. Pull through about one inch. Replace cover. Pull out first wipe and tear off at an angle. Remaining wipes feed automatically, ready for the next use. When not in use, keep center cap closed to prevent evaporation.

{For flat pack dispensing:}

Dispensing Directions:

Pull back re-sealable label located on top of pack top about 3/4 of the way. Do not completely remove the label from pack. Remove wipe. Reseal with label to prevent evaporation of solution. To prevent evaporation keep pack sealed when not in use.

Cleaning and Disinfection Instructions:

First, remove animal from immediate area; then remove all visible debris, such as animal excrement, and bedding materials, such as blankets, litter, wood chips, hay or straw, and drinking and feeding utensils.

Use a fresh Opti-Cide-3 Wipe to pre-clean surfaces of all gross filth and heavy soil. Repeat as necessary until surfaces are visibly clean. To effectively disinfect the pre-cleaned surfaces, use a fresh [new] Opti-Cide-3 Wipe to thoroughly wet the surfaces and allow surfaces to remain wet for 3 minutes [5 minutes for canine parvovirus appears in the label claims] at room temperature (69°F/20°C). Use enough wipes to ensure that the surface remains wet for the three-minute [five-minutes for canine parvovirus] contact time. Allow surfaces to air dry before use, or if desired, rinse surface after 3 minutes [5 minutes for canine parvovirus appears in the label claims] using potable water and wipe or air dry. For disinfection of Avian Influenza A, use this product only for surfaces that 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).

HBV, HCV and HIV-1 Precautions: Opti-Cide 3 effectively inactivates HBV, HCV and HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care or other settings in which

8/9

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 HBV, HCV and/or the human immunodeficiency virus Type 1 (HIV-1) associated with AIDS. **Special instructions for cleaning and decontamination against HBV, HCV 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 [5 minutes for canine parvovirus] 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.

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 regular trash disposal. Do not reuse wipes or empty container. **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.
<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.

9/9

For product or technical information contact Micro-Scientific Industries at 1-888-253-2536.

**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