



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

FEB 06 2010

Attention Kim Davis
Regulatory Manager

Subject Notification
Opti-Cide 3 Wipes ®
EPA Registration No 70144-2
Amendment Letter dated January 6, 2010

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

- Revising your product label to incorporate the Influenza H1N1 claim

The Notification is in compliance with PR Notice 98-10 and is acceptable If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062

Sincerely,

A handwritten signature in black ink, which appears to read "M. Swindell", is positioned above the printed name.

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

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="font-size: 2em; font-weight: bold;">Notification</div>
Application for Pesticide – Section I			
1 Company/Product Number <div style="text-align: center;">EPA Reg No 70144-2</div>		2 EPA Product Manager <div style="text-align: center;">Marshall Swindell</div>	
4 Company/ Product (Name) <div style="text-align: center;">Opti-Cide® 3 Wipes</div>		3 Proposed Classification <div style="display: flex; justify-content: space-between;"> <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted </div>	
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 type="checkbox"/> Final printed labels in response to Agency letter dated _____ <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) <div style="text-align: center; font-weight: bold;">Submit label revision notification to add Pandemic 2009 H1N1 Influenza A Virus claims per PR Notice 95 2</div> <div style="text-align: center;">(Refer to the Reference Label for an illustration of label revisions)</div> <i>This notification is consistent with the provisions of PR Notice 95 2 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 95 2 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 type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input 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 <div style="text-align: center;">Kim Davis, CC, APC, Manager</div>		Title <div style="text-align: center;">Consultant/Agent</div>	
		Telephone No (Include Area Code) <div style="text-align: center;">(970) 353-0611 kim@regwest.com</div>	
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.			5 Date Application Received <div style="text-align: center; font-weight: bold;">(Stamped)</div>
2 Signature 		3 Title <div style="text-align: center;">Consultant/Agent</div>	
4 Typed Name <div style="text-align: center;">Kim Davis, CC, APC, Manager</div>		5 Date <div style="text-align: center;">January 6, 2009</div>	

FedEx

Non-PRIA Label Revision (H1N1) Notification

3 7 8
FTN 8675 7596 5830



January 6, 2009

Mr Marshall Swindell Product Manager 33
Document Processing Desk – **NOTIF**
Office of Pesticide Programs – **7504C**
U S Environmental Protection Agency
One Potomac Yard South Building Room S 4900
2777 South Crystal Drive
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 a notification of label revision 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)
- 2 Two **New Labels** (incorporating the revisions)

Per the Agency's guidance document entitled 'Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)' and the referenced PR Notice 95 2, we are adding the labeling recommendations as presented in the guidance document We are also deleting the website from the label All revisions are illustrated on the **Reference Label**

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

Regards
RegWest Company, LLC



Kim Davis CC APC Manager
Consultant/Agent

Attachments

cc MSI – Wager J

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

Opti-Cide® 3 Wipes

{ABN Opti Cide 3 Surface 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 • Tuberculocidal

Disinfectant Cleaner [and] Deodorizer

Disinfects Cleans Deodorizes

Kills Bacteria, Viruses, Fungi [in 3 minutes*]

[*Except for Canine Parvovirus in 5 minutes]

Kills Pandemic 2009 H1N1 Influenza A Virus* [formerly called "swine flu"]

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

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]
 - Canine Para Influenza Virus [ATCC VR 666]
 - 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
 - Methicillin Resistant *Staphylococcus aureus* (MRSA) [ATCC 33591]
 - *Mycobacterium bovis* BCG (tuberculosis) (TB)
 - Pandemic 2009 H1N1 Influenza A Virus*
 - 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 pre cleaned 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 automobile interiors autopsy rooms barber shops bathrooms blood centers buses cadaver work [processing] areas cardiac care labs cardiac catheterization labs cardiology units central sterile supply central supply areas child care facilities (day care, infant care schools) 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 food processing

facilities (non food contact surfaces) funeral homes GI laboratories gyms hair salons health clubs 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 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 plasma pheresis centers surgical centers) 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 police vehicles prisoner holding areas [lockups] prisons radiology centers research laboratories respiratory care units salons (beauty manicure/pedicure tanning tattoo) schools skin care facilities small animal/pet care facilities spas surgical centers and rooms trailers train cars transport equipment veterinary facilities veterinary hospitals workout rooms zoologic centers zoos and areas/facilities concerned with the hazards of cross contamination from infectious microorganisms

Opti Cide 3 Wipes may be used on ambulance equipment and [patient care] surfaces anesthesia equipment surfaces animal cages (aviary canine feline etc) animal examination tables animal habitats athletic/training facility surfaces baby/infant care surfaces backboards bassinets bathing units bed rails beds blood pressure devices breathing masks cabinets cages canine care surfaces, changing tables commodes computer keyboards [surfaces] counters CPR training devices CT equipment/surfaces curing lights dental equipment surfaces/devices dialysis machine surfaces diving equipment and air packs doorknobs 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 firefighter turnout gear foot spa surfaces funeral home surfaces goggles gonial lenses hard cervical collars/braces helmets hospitality and hotel surfaces incubators infant care equipment (bassinets bed railings, cribs, incubators tables warmers (exterior surface), instrument stands Isolettes^o kennel cages kennels keyboards kidney machines laboratory equipment/surfaces laminated surfaces large animal care surfaces light lens covers litter boxes loupes mats manicure/pedicure tables/chairs mannequins mayo stands medical equipment surfaces/devices microkeratome surfaces microscopes monitor knobs monitors morgue tables MRI equipment surfaces neonatal/nursery surfaces non critical devices nursing station surfaces OB [obstetrical equipment] surfaces, occupational therapy devices, office fixtures, OR lights OR surfaces OR tables ophthalmic equipment surfaces/devices optical wear (excluding contact lenses) oxygen hoods oxygen tents painted surfaces patient bed surfaces patient care devices patient care equipment surfaces patient examination tables, patient stretchers, patient transport surfaces pet care surfaces pharmacy surfaces physical therapy equipment (such as bars chairs empty whirlpool tanks etc) play care equipment play mats pulmonary function equipment pumps radiology equipment surfaces rails refrigerators (exterior surface) reptile care surfaces respirators respiratory care equipment surfaces respiratory therapy equipment shampoo bowls ship [river ocean sea vessel] surfaces, showers [floors/walls] sink faucets skin care equipment/surfaces sinks small animal care surfaces spirometers stalls stair chairs stretchers surgical equipment surfaces surgical microscopes tables tanks tanning bed surfaces tattooing equipment surfaces/devices telephones, toilets (rims seats and exterior surfaces) toys transport van surfaces transportation equipment surfaces turn out gear ventilators walls warmers (exterior surface) wet/dry suits wheel chairs whirlpool surfaces work stations wrestling mats X ray equipment/surfaces and devices/surfaces potentially contaminated with disease causing microorganisms [and use sites made of glass, metal Plexiglas^o plastics (i.e polycarbonate polypropylene polyvinylchloride and polystyrene) baked on painted surfaces stainless steel and non porous vinyl]

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A Virus* This product Opti Cide 3 Wipes is a broad spectrum hard surface disinfectant that has been shown to be effective against Avian Influenza A Virus ATCC VR 2072 and Influenza Virus Strain A2/Hong Kong as is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 Influenza virus*

This product has demonstrated effectiveness against Influenza A Virus* and is expected to inactivate all influenza A Viruses including Pandemic 2009 H1N1 Influenza virus*

This product has demonstrated effectiveness against Avian Influenza Virus ATCC VR 2072 and Influenza Virus Strain A2/Hong Kong and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu)

{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] 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] 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) Food preparation surfaces must be rinsed with potable water prior to use

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 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 and Container Disposal** Dispose of wipe in trash after use Do not flush Tightly close lid between uses to retain moisture **Nonrefillable container** Do not reuse or refill this empty container Offer empty container for recycling If recycling is not available discard container in trash

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 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

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

Order No _____

[] Denotes alternate language

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