

70144-2

02/11/2008

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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

FEB 11 2008

Attention: Kim Davis
Regulatory Manager

Subject: Opti-Cide-3 Wipes
EPA Reg. No. 70144-2
Amendment Application Date: June 8, 2007

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided the following label revisions are inserted:

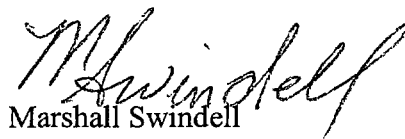
- There are currently no registered products that have claims as disinfectant used in ventilation systems (the use site listed in your reference label). Efficacy data needs to be submitted to support these claims. EPA requires that registrants proposing this claim submit an acceptable test method that shows the product is effective in treating pathogenic organisms in ventilation systems.
- Use sites listed that make reference to treatment of "food preparation surfaces (with potable water rinse)" need to be removed. "This disinfection claim is not supported by data. In addition, this use needs Food and Drug Administration approval before it can be added to this label.
- For the listed use sites "refrigerators" and "warmers", in parentheses, add the wording (exterior surface).
- The Agency request that you delete the *C. difficile* claim from your label. The Agency has re-evaluated its acceptance of *Clostridium difficile* (vegetative form) on previously accepted claims and requests for new claims. Peer-reviewed scientific literature and case studies have consistently demonstrated that the *C. difficile* spore is the source of *Clostridium difficile*-associated disease (CDAD),

and is an immediate public health concern. After careful consideration, the Agency is certain that claims against the vegetative form of *C. difficile* are misleading (40 CFR 156.10(a) (5), and imply heightened efficacy. The Agency considers antimicrobial pesticides to be unique because of the critical nature of the threat to public health that may result from ineffective use of products due to obsolete or misleading labeling. As a result, any reference to claims of effectiveness against *Clostridium difficile* (vegetative) OR *Clostridium difficile* (without having supporting data against *C. difficile* spores) are unacceptable. To address the growing need for products in hospital/medical setting, the Agency is moving expeditiously to develop an appropriate test system and performance standards for *Clostridium difficile* (spores).

- All references to the wording "et cetera" (etc) and "other" needs to be removed. A reference such as this word is broad and could imply a variety of meanings or interpretations.

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

Sincerely,



Marshall Swindell

Product Manager (33)

Regulatory Management Branch 1

Antimicrobials Division (7510C)

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, Fungi [in 3 minutes]

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% 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 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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

{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

701442-2

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- Canine Parvovirus

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, 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],

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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 other 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, food preparation surfaces (~~with potable water rinses~~), 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, etc.), instrument stands, Isolettes®, 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, 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 other exterior surfaces), toys, transport van surfaces, transportation equipment surfaces, turn-out gear, ~~ventilation systems~~, ventilators, walls, warmers, wet/dry suits, wheel chairs, whirlpool surfaces, work stations, wrestling mats, X-ray equipment/surfaces and ~~other~~ devices/surfaces potentially contaminated with disease-causing microorganisms (and ~~also~~ 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.]

(exterior surface)

(exterior surface)

{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.

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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.~~ 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 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 ~~water~~ **ACCORDING TO** water after handling. Remove contaminated clothing and wash clothing before reuse.

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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

www.opticide.com

Order No: _____

[] Denotes alternate language

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

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