

70144-2

04/11/2007

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U.S. ENVIRONMENTAL PROTECTION  
AGENCYOffice of Pesticide Programs  
Antimicrobials Division (7510P)  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460

EPA Reg.

Number:

70144-2

Date of

Issuance:

APR 11 2007

Term of Issuance:

**Conditional**

Name of Pesticide Product:

Opti-Cide-3 Wipes

## NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Kim Davis

RegWest Company

Consultant for Micro-Scientific, Inc.

30856 Rocky Road

Greely, CO 80631-9375

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration 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.

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 sec 3(c)(7)(a) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 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.
2. Make the labeling changes listed below before you release the product for shipment:
  - a. Revise the "EPA Registration Number to read, "EPA Reg. No. 70144-2".

Signature of Approving Official:

Marshall Swindell  
Product Manager Team-33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Date:

APR 11 2007

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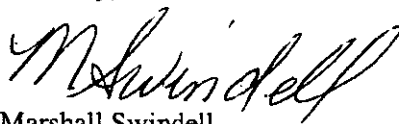
EPA Reg. No. 70144-2

- b. The proposed label claims are acceptable regarding the use of the product, Opti-Cide 3 Wipes, as a disinfectant with virucidal claims against Canine Parvovirus with a contact time of 5 minutes. It is recommended that reference to the 5 minute contact time for Canine Parvovirus be added to page 2 of the proposed label the same way it is listed next to Vancomycin-Resistant Enterococcus Faecium (VRE).
- c. Asterisks are provided for numerous organisms on the proposed label. Please remove or provide explanation/legend for the asterisks.
- d. Verbiage must be added to the label requiring the consumer to "use enough wipes to ensure that the surface remains wet for three-minute contact time".
- e. The designation of "*Salmonella choleraesuis*" has been changed to "*Salmonella enterica*" effective immediately. This change should be reflected on the proposed label.
- f. Include HCV and HBV in the special instructions section for HIV. Since both HCV and HBV are bloodborne pathogens, special instructions are required for disinfection and disposal of contaminated areas.
- g. Isopropanol is listed as an active ingredient for Opti-Cide 3 Wipes. The percentage of isopropanol used in the formulation was 21.000%. At this percentage, antimicrobial properties are not exhibited. Please remove isopropanol from the list of active ingredients.
- h. For Avian Influenza A claims, it should be made clear that the product's use is only for surfaces which 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).
- i. On page 3 of 5, in the section that states "**Cleaning and Disinfection Instructions**", remove the wording "cage or".

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,



Marshall Swindell  
Product Manager Team-33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Enclosure: (Stamped Label)

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## Opti-Cide®-3 Wipes

Disinfectant/Cleaner

Veterinary/Animal Care Facility Disinfectant/Cleaner

Medical/Surgical/Dental Equipment Disinfectant Cleaner and Decontaminant

Bactericidal • Fungicidal • Virucidal\*

### Active Ingredients:

n-Alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> )	
dimethyl benzyl ammonium chloride .....	0.154%
n-Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> ) 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 [side] panel for additional precautionary statements.

EPA Reg. No. 70144-\_\_\_\_\_ EPA Est. \_\_\_\_\_

Net Contents: \_\_\_\_\_ wipes  
Net Weight: \_\_\_\_\_ oz. (\_\_\_\_\_ g)

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

Product Order Number: \_\_\_\_\_

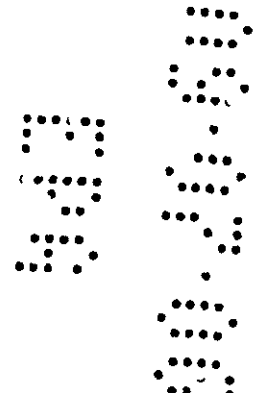
APR 11 2007  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 70144-2

{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\*
- *Clostridium difficile* 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 choleraesuis* 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

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10144-2

### 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 care facilities, animal 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, human transport vehicles, infant care units, institutional facilities, intensive care units, isolation rooms, 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, animal examination tables, animal habitats, back boards, basins, bed rails, beds, breathing masks, cages, canine care surfaces, commodes, computer keyboards, counters, dialysis machine surfaces, door knobs, EMS equipment/work surfaces, endoscopic devices, equipment surfaces, ER surfaces, examination tables, eye

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glasses, eye protection devices, feline care surfaces, finished surfaces, foot spas, funeral home surfaces, goggles, helmets, 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, 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, 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, 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 a 90° 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 {when canine parvovirus appears in the label claims}] at room temperature (69°F/20°C). The use of additional wipes may be necessary to keep surface visibly wet during the required contact time. Allow surfaces to air dry before use, or if desired, rinse surface after 3 minutes [5 minutes {when canine parvovirus appears in the label claims}] using potable water and wipe or air dry.

**HIV-1 Precautions:** Opti-Cide 3 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, gown, and 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 [5 minutes {when canine parvovirus appears in the label claims}] prior to

Under the Federal Insecticide, Fungicide, and Rodenticide Act, amended, for the pesticide, registered under EPA Reg. No. 2007-170144-2

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

<b>If Inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> </ul>
<b>If on Skin or Clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>
<b>If in Eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
<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.

**Manufactured in the U.S.A. for:**

Micro-Scientific Industries, Inc.

[Corporate Offices:] 1225 Carnegie Street; Rolling Meadows, IL 60008

Telephone: 1-888-253-2536

www.opticide.com

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Order No: \_\_\_\_\_

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- [ ] Denotes alternate language
- { } Denotes language that does not appear on the market label