



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

April 6, 2020

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Subject: Label Amendment – Emerging Viral Pathogens Claim  
Product Name: Opti-Cide 3 Wipes  
EPA Registration Number: 70144-2  
Application Date: February 7, 2020  
Decision Number: 560567

Dear Megan:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), [https://www.epa.gov/sites/production/files/2016-09/documents/emerging\\_viral\\_pathogen\\_program\\_guidance\\_final\\_8\\_19\\_16\\_001\\_0.pdf](https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf), you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
    - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
      - A. CDC Current Outbreak List for “U.S. Based Outbreaks” ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)),
      - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)) (also released through the CDC’s Health Alert Network (HAN) notification process)
      - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page ([www.cdc.gov/hai/outbreaks](http://www.cdc.gov/hai/outbreaks))
    - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page ([www.oie.int/wahis\\_2/public/wahid.php/Diseaseinformation/WI](http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI)).
      - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is small non-enveloped, large non-enveloped, enveloped.
      - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Rhinovirus, Rotavirus and Murine Norovirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact disinfectants list at [disinfectantslist@epa.gov](mailto:disinfectantslist@epa.gov).

Sincerely,



Demson Fuller, Product Manager 32  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: stamped label

**ACCEPTED**

04/06/2020

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

Opti-Cide® 3 Wipes  
EPA Reg. No. 70144-2  
A570 Label Amendment to add Emerging Viral Pathogens Claim  
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# Opti-Cide® 3 Wipes

{Alternate Brand Names:} [Opti-Cide® 3 Surface Wipes] [Opti-Cide® 3 Disinfectant Surface Wipes] [Opti-Cide® 3 Disinfecting Surface Wipes] [Opti-Cide® 3 V Surface Wipes] [Opti-Cide® Surface Wipes] [Opti-Cide® 1 Surface Wipes] [Opti-Cide® 2 Surface Wipes]

{Insert marketing statements, as appropriate, from *Marketing Copy* and/or *Directions for Use*}

**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 ([First Aid] [and] [additional Precautionary Statements.])]

EPA Reg. No. 70144-2

EPA Est.

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



{Flag image is optional}  
[Made in the U.S.A.]

[ ] Denotes optional language

( [ ] ) Denotes one of the options within the brackets must be chosen

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

( ) Denotes language that is intended to be included on label with parenthesis included

The phrase "This product" may be replaced with the appropriate product name or "these towelettes", "these wipes"

{Marketing Copy}

**{General Marketing Claims}**

- Antibacterial
- Antimicrobial Cleaner
- Cleans
- Cleaner
- Deodorizer
- Fragrance free {note: for use only with formulas without fragrance}
- Hospital disinfectant
- Healthcare uses
- Housekeeping uses
- In-home [Hospice] [Healthcare] [Use]
- Spot Cleans

([These wipes][These towelettes]) are disposable, single-use towelette wipes pre-saturated with ([Opti-Cide® 3][Opti-Cide® 1][Opti-Cide® 2][disinfectant]) solution. Pre-cleaning ([Instrument] [device]) Wipe

{(With) (Contains)} Lemon {or appropriate descriptive term} Scent *{note: for use only with lemon fragrance formulas}*

{(With) (Contains)} Rust Inhibitor, Biodegradable Detergent *{note: for use only with applicable formulas}*

Use On Pet Care Surfaces

XL

Extra Large



*{Insert Applicable Percentage Here}*% Larger Wipes

*{Insert Current Wipe Size Here}* Compared To Traditional *{Insert Previous Wipe Size Here}*

### ***{Disinfectant Marketing Claims}***

Bactericidal

Broad Spectrum Disinfectant

Fungicidal

Germicidal

Disinfectant

Disinfectant [ / ] Cleaner {or} Cleaner [ / ] Disinfectant

Disinfecting Cleaner

Disinfects Hard, Non-porous Surfaces in ([2] [3] [5]) {as appropriate} minutes

Disinfects

Kills ([Tuberculosis, BCG [(var. bovis)], [TB]], [[Gram-positive and Gram-negative] Bacteria], [[Enveloped & Non-Enveloped] Viruses\*], [Fungi]) in [2] [3] [5] minutes

Kills ([Bacteria,] [Viruses\*], [Fungi,] [*Mycobacterium-tuberculosis* [(var. bovis)]) in ([2][3][5]) minutes as directed {use with appropriate disinfectant/virucidal claims}

Kills ([Bacteria,] [Viruses\*], [Fungi]) on pre-cleaned, hard, non-porous surfaces such as {select from use sites}

Kills {insert organism from list of approved organisms}

Kills Flu Viruses

Kills ([99.9% of bacteria] [germs])

Tuberculocidal

Virucidal\*

([Veterinary]/[Animal]/[Pet Care]) Facility Disinfectant/Cleaner

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

([Medical]/[Surgical]/[Dental] [Veterinary]) Equipment Surface Disinfectant Cleaner

One product ([to] [clean[s]], [and] [sanitize[s]], [and] [disinfect[s]])

This product is effective for [cleaning], [sanitizing], [and] [disinfecting]

[Hard, Non-Porous Surface] Disinfectant Cleaner

{Insert use site or surface} Disinfectant Cleaner

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A Virus.

This product 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 and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza virus.

This product is intended for use on pre-cleaned, hard, non-porous surfaces in areas where the disinfection of surfaces is required.

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"].

[Two minute] [Three minute] [Five minute] {as appropriate} Hard, Non-Porous Surface Disinfectant *{Note to Reviewer: The numerals "2", "3", "5" may be used in place of "Two", "Three", "Five"}*

### **{Sanitization Marketing Claims}**

Sanitizer

Sanitize[s]

10 Second Hard, Non-Porous Surface Sanitizer

Sanitizes hard, non-porous [non-food contact] surfaces in 10 seconds

Non-Food Contact Sanitizer

([Animal] [/] [Veterinary][/][Pet Care]) Facility Sanitizer

Kills 99.9% of *Staphylococcus aureus* and *Enterobacter aerogenes* in 10 Seconds on Hard, Non-porous Non-Food Contact Surfaces

For use on hard, non-porous non-food contact surfaces

### **{Use Sites:}**

*{Note: If listing Use Sites from this section, the phrase beginning with "This product..." below must be included}*

([This product] [These towelettes][These wipes]) can be used ([in][at]) the following locations: ambulances, animal transport vehicles, animal/pet care facilities, animal/pet housing facilities, animal labs, athletic clubs, automobile interiors, autopsy rooms, barber shops, bathrooms, beauty salons, blood centers, buses, cadaver 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, healthcare facilities, 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, manicure/pedicure salons, medical facilities, blood ([banks [centers]], clean rooms, dental offices, drug preparation rooms, emergency rooms, 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, offices, ophthalmic centers, paramedic ([squads][units]), pathology facilities, pheresis equipment and centers, podiatry offices, police vehicles, prisoner holding ([areas] [lockups]), prisons, radiology centers, research laboratories, respiratory care units, salons, schools, skin care facilities, small animal/pet care facilities, spas, surgical centers and rooms, trailers, tanning salons, tattoo studios, 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.

### **{Surfaces:}**

*{Note: If listing Surfaces from this section, the phrase beginning with "This product..." below must be included}*

*{Note: If listing endoscopes or endoscope surfaces, the "For use to[pre-clean] [pre-treat] flexible endoscopes prior to handling during terminal reprocessing" Directions for Use must be used}*

([This product] [These towelettes][These wipes]) may be used on the following surfaces: 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, glucometers, glucose meters, goggles, gonial lenses, hard cervical collars/braces, helmets, hospitality and hotel surfaces, incubators, infant care equipment (bassinets, bed railings, cribs, infant incubator-surfaces, 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, medication infusion surfaces 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, pet care equipment, 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 surfaces, ([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®, plastics (i.e., polycarbonate, polypropylene, polyvinylchloride and polystyrene), clear plastic, baked-on painted surfaces, stainless steel, brass, chrome, copper, acrylic, [and non-porous] vinyl], powder painted coated surfaces, baked painted surfaces, Formica®, glazed tile, leather, laminated surfaces [and other [frequently touched] [high-touched],[similar] ([surfaces])[areas)].

**{Graphics and Icons}**

{Note to the reviewer: The following images may appear on the market label or product as additional marketing copy in any color. The “clock” symbols can be used when referring to disinfecting claims.}



{End of Marketing Copy}

## 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!**

Pre-clean all surfaces to be treated with this product. Apply this product by wiping to thoroughly wet hard, non-porous surfaces.

{Kill Claims:}

### [Hard, Non-Porous Non-Food Contact Surface Sanitization]

This product kills the following microorganisms in 10 seconds on pre-cleaned hard, non-porous surfaces at room temperature when used as directed:

- *Staphylococcus aureus* {ATCC 6538}
- *Enterobacter aerogenes* {ATCC 13048}

### [Hospital and General Disinfection] {or} [Bactericidal]:

This product kills the following bacteria in 2 minutes on pre-cleaned hard, non-porous surfaces at room temperature when used as directed:

- *Acinetobacter baumannii* {ATCC 19606}
- *Escherichia coli* – with [(extended beta-lactamase resistance) [(ESBL)]] [(*E. coli*)] {ATCC BAA-196}
- *Enterobacter aerogenes* {ATCC 13048}
- Carbapenem-resistant *Klebsiella pneumoniae* [(CRKP)] {ATCC BAA-1705}
- *Listeria monocytogenes* {ATCC 19117}
- Methicillin-Resistant *Staphylococcus aureus* [(MRSA)] {ATCC 33591}
- *Mycobacterium bovis*, BCG [(tuberculosis)] [(TB)] {Organon Teknika Corp}
- *Pseudomonas aeruginosa* {ATCC 15442}
- *Salmonella enterica* {ATCC 10708}
- *Serratia marcescens* {ATCC 14756}
- *Staphylococcus aureus* {ATCC 6538}
- Vancomycin – Resistant *Enterococcus faecium* [(VRE)] {ATCC 51559}

### [Virucidal\*]

This product kills the following viruses\* in 2 minutes on pre-cleaned hard, non-porous surfaces at room temperature when used as directed:

- Avian Influenza A Reassortant Virus [(H3N2)] {ATCC VR-2072}
- Rotavirus [Strain WA]
- Hepatitis B Virus\* [(HBV)] [Strain LeGarth]
- Hepatitis C Virus\* [(HCV)]
- Herpes Simplex II Virus [(HSV 2)] [G Strain]
- Human Immunodeficiency Virus\* [(HIV-1)] [(associated with AIDS)]
- Swine Influenza A Virus [(H1N1)] [Strain A/Swine/Iowa/15/30] [(formerly called “swine flu”)] {ATCC VR-333}
- Influenza A Virus [Strain A2/Hong Kong] {ATCC VR-544}
- Rhinovirus [Type 14] [RV-14] {ATCC VR-284}

### [Fungicidal]

This product kills the following fungi in 2 minutes on pre-cleaned hard, non-porous surfaces at room temperature when used as directed:

- *Trichophyton interdigitale* [(formerly known as *Trichophyton mentagrophytes*)] [(ringworm)] [(Athletes Foot)] {ATCC 9533}



[For Veterinary / Pet Care Use:]

**[Disinfection {or} Bactericidal]**

[In addition to the other microorganisms listed on this label] This product kills the following bacteria in 3 minutes on pre-cleaned hard, non-porous surfaces at room temperature when used as directed:

- *Bordetella bronchiseptica* [(kennel cough)] {ATCC 10580}
- *Chlamydia psittaci* [(parrot fever)]
- *Streptococcus equi* [(Strangles)] [(equine distemper)] {ATCC 33398}

[For Veterinary / Pet Care Use:]

**[Virucidal\*]**

[In addition to the other microorganisms listed on this label] This product kills the following viruses\* in 3 minutes on pre-cleaned hard, non-porous surfaces at room temperature when used as directed:

- Bovine Viral Diarrhea Virus\* [BVDV–Hepatitis C Virus\* Surrogate]
- Duck Hepatitis B Virus\* [DHBV–Hepatitis B Virus\* Surrogate] [Strain LeGarth]
- Canine Distemper Virus {ATCC VR-128}
- Canine Para-Influenza Virus {ATCC VR-666}
- Feline Leukemia Virus {American Bioresearch (CrFK cells)}
- Infectious Bovine *Rhinotracheitis* Virus {ATCC VR-188}
- Murine Norovirus [Strain MNV-G]

This product kills the following virus\* in 5 minutes on pre-cleaned hard, non-porous surfaces at room temperature when used as directed:

- Canine Parvovirus

*{Contact time listed on the market label will be based on label claims and individual microorganism contact times.}*

**[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.

**[For individual pack dispensing:]**

**Dispensing Directions:**

Open packet, remove and use.

*{The following paragraph must be included when farm premise uses are used:}*

**[Additional Special Animal /Veterinary/Pet Care Cleaning ([Sanitizing] [Disinfection]) of Surface Instructions:]**

First, remove animals and feed 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. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with this product and rinse with water. Then treat applicable surfaces with this product. Treated surfaces must remain wet for 5 minutes to kill all microorganisms listed on this label. Ventilate buildings, cars, trucks, boats and other closed spaces. Do not house animals or employ equipment until treatment has set, dried or absorbed. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waters with soap or detergent.

*{The following paragraph is required when the product is for small, non-farm animal care facility uses:}*

Prior to surface cleaning and disinfection, remove visible debris such as animal excrement and bedding materials such as blankets, litter, wood chips, hay or straw.

*{The following paragraph is required when the Avian Influenza A kill claim appears on the label:}*

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 and drink dispensing and preparation surfaces must be rinsed with potable water prior to use.

*{The following paragraph is required when the label bears HIV-1, HBV, and/or HCV kill claims:}*

**\*HIV-1, HBV, and HCV Precautions:** This product kills HIV-1, HBV, and HCV pre-cleaned hard, non-porous surfaces/objects previously soiled with blood/body fluids in health care or other settings in which there is an expected likelihood of soiling of hard, non-porous surfaces/objects with blood/body fluids, and in which the surfaces/objects can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 [(HIV-1)] [(associated with AIDS)], Hepatitis B Virus [(HBV)], and Hepatitis C Virus [(HCV)].

**Special instructions for cleaning against HIV-1, HBV, and HCV on surfaces/objects soiled with blood/body fluids:**

**Personal Protection:** Wear appropriate barrier protection including gloves, gowns, masks and eye coverings.

**Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces/objects before disinfection.

**Contact Time:** Allow hard, non-porous surfaces to remain wet for 2 minutes to kill HIV-1, HBV, and HCV.

**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.

*{The following paragraph is required with the product bears human medical use sites/articles/surfaces:}*

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 critical and semi-critical medical devices prior to sterilization or high-level disinfection.

## **[Cleaning Directions]**

**For Surface Cleaning:** To clean surfaces, use a fresh ([wipe] [towelette]) on surfaces. Repeat as necessary until surfaces are visibly clean.

*{Note to reviewer: Should endoscopes be chosen as a surface, the following Directions for Use paragraph is required}*

**For use to ([pre-clean] [pre-treat]) flexible endoscopes prior to handling during terminal reprocessing:** Immediately after use and while the scope is still connected to the light source, thoroughly wipe the exterior surface of the insertion tube with this product until visibly clean. Cover the scope and transport to the appropriate area for terminal reprocessing. **This product is not be used as a sanitizer or disinfectant for endoscopes.**

**[Disinfection Directions]**

For use as a hard, non-porous non-food contact surface disinfectant/virucide/fungicide: Pre-clean hard, non-porous surfaces to be disinfected with a clean wipe. Use a fresh, clean wipe to disinfect hard, non-porous surfaces until thoroughly wet. Allow surfaces to remain wet for ([2] [3] [5]) {as appropriate} minutes [at room temperature].

**[Sanitization Directions]**

For hard, non-porous non-food contact surface sanitization: Pre-clean hard, non-porous surfaces with a clean wipe. Use a fresh, clean wipe to sanitize hard, non-porous surfaces until thoroughly wet. Allow surfaces to remain wet for 10 seconds [at room temperature].

**Storage and Disposal**

Do not contaminate food or feed by storage or disposal.

**Storage:** Store in a cool, well-ventilated area. **Product Disposal:** Dispose of wipe in trash after use. Do not flush. Tightly close lid between uses to retain moisture. **Container Disposal:** Non-refillable 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. Wear appropriate personal protective equipment based on safe work practices. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. 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</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>

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 (*insert appropriate emergency contact number*) for emergency medical treatment information [the National Pesticides Information Center (NPIC) at 1-800-858-7378 for non-emergency information concerning this product].

{The First Aid statements may appear in grid or paragraph format.}

**Physical or Chemical Hazards**

Do not use or store near heat or open flame.

**[For product or technical information contact {insert appropriate contact information}].**

**Manufactured in the U.S.A. for:  
 Micro-Scientific, LLC**

[Corporate Offices:] 755 Tri-State Parkway, Gurnee, IL 60031 U.S.A.  
 Telephone: 1-888-253-2536

[Product] [Code] [Re-order] [Product Code][Order] [No]: \_\_\_\_\_

[Opti-Cide® is a registered trademark of Micro-Scientific, LLC.]

### Emerging Viral Pathogens Claim

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses
- Small Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...following the directions for use for the following supporting organism(s) on the label:
Enveloped virus	Rhinovirus [Type 14] [RV-14] {ATCC VR-284} Rotavirus {Strain WA}
Large, non-enveloped virus	Rhinovirus [Type 14] [RV-14] {ATCC VR-284}
Small, non-enveloped virus	Rhinovirus [Type 14] [RV-14] {ATCC VR-284} Murine Norovirus [Strain MNV-G]

[Product Name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [Product Name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product Name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.