

70144-1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

10/3/2011

10/13

OCT - 3 2011

Jack Wagner, D. Sc., MSc.PH
 Micro-Scientific Industries, Inc.
 1225 Carnegie Street 101
 Rolling Meadows, IL 60008

Subject: Opti-Cide 3
 EPA Registration No.: 70144-1
 Amendment Date: May 12, 2011
 EPA Receipt Date: May 13, 2011

Dear Mr. Wagner,

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below:

- Addition of directions for use and marketing claims
- Addition of public health organisms with supporting data

Submitted Data

The following efficacy studies have been submitted in support of this application.

Study	MRID Number	Status
Disinfectant: <i>Staphylococcus aureus</i>	484820-03	Acceptable undiluted pre-cleaned surface for 2 minute contact time
Disinfectant: <i>Salmonella enterica</i>	484820-03	Acceptable undiluted pre-cleaned surface for 2 minute contact time
Disinfectant: <i>Pseudomonas aeruginosa</i>	484820-03	Acceptable undiluted pre-cleaned surface for 2 minute contact time
Disinfectant: Vancomycin-resistant <i>Enterococcus faecalis</i>	484820-07	Acceptable undiluted pre-cleaned surface for 2 minute contact time
Disinfectant: Methicillin-resistant <i>Staphylococcus aureus</i>	484820-08	Acceptable undiluted pre-cleaned surface for 2 minute contact time
Disinfectant: <i>Trichophyton mentagrophytes</i>	484820-09	Acceptable undiluted pre-cleaned surface for 2 minute contact time
Bovine viral diarrhea virus	484820-11	Acceptable undiluted 5% soil load for 2 minute contact time
Duck Hepatitis B virus	484820-10	Acceptable undiluted 100% soil load for 2 minute contact time

CONCURRENCES

SYMBOL	7510P						
SURNAME	J. J. J.						
DATE	10/3/11						

<i>Mycobacterium bovis</i> BCG	484820-04 and 484820-05	Acceptable undiluted pre-cleaned surface for 2 minute contact time
<i>Mycobacterium bovis</i> BCG (confirmatory data)	484820-06	Acceptable undiluted pre-cleaned surface for 2 minute contact time
Non-Food Contact Sanitizer: <i>Staphylococcus aureus</i> and <i>Enterobacter aerogenes</i>	484820-01	Acceptable undiluted pre-cleaned hard surfaces for 10 second contact time
Non-Food Contact Sanitizer: <i>Staphylococcus aureus</i> and <i>Enterobacter aerogenes</i>	484820-02	Acceptable undiluted pre-cleaned soft surfaces for 10 second contact time

Please note the following:

Data was **not** provided to support a 2 minute contact time for the following organisms: Herpes simplex II virus, Human immunodeficiency virus, and Influenza virus, Strain A2/Hong Kong. As such, your label must include a 3 minute contact time associated with these organisms. Revise page four by deleting Herpes simplex II virus, Human immunodeficiency virus, and Influenza virus, Strain A2/Hong Kong from the listing associated with a 2 minute contact time and placing these three organisms in the 3 minute contact time list.

Conditions

Revise the label as follows:

1) Your label must be written to assure that the correct contact time is associated with the corresponding list of organisms. Revise the statement on page one to include the following symbols which will be associated with the corresponding organism list. Revise to read: "Disinfectant [Disinfects] [in 2 ## [3 °° or 5 *** {as appropriate}] minutes]" Revise page four by placing the "##" symbol next to the Two-minute contact time list, "°°" next to the Three-minute contact time list, and "***" next to the 5-minute contact time list. Make this correction to the "Surface Disinfection" section on page six, the "For Cleaning and Disinfecting Dental Impressions" section on page seven as well as the "[For Use as a] Non-Critical Medical Item Disinfection Immersion Solution" sections on page seven.

2) Revise the inaccurate statement on page one. Your product does not kill 99.9 % of germs (bacteria, fungi and viruses.) Revise to state: "Kills [99.9% of Bacteria] {or} [Germs]" In addition, delete the " ** " which precedes the statement: "Kills 99.9% of *Staphylococcus aureus* and *Enterobacter aerogenes*" as it is inaccurate to associate this statement with the term "germs."

3) Delete the following statement on page two: "With [Contains] Biodegradable Detergent". Delete this claim as it is false and misleading. The Agency is in the process of issuing guidance on this claim. The criteria for acceptance Biodegradable Surfactant or 100% Biodegradable Formula claims will be posted in the next few weeks. Delete this claim at this time.

CONCURRENCES

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4) This product is supported by data as a non-food contact sanitizer. As such, the following clarifying statement must accompany this product when the sites "drug preparation equipment" and/or "drug preparation hoods" are included on the label. Add the following statement in association with these sites: *"Do not use on surfaces that have direct contact with drugs."*

5) The listing of organisms and associated contact times on page four and five are considered directions for use of the product. Revise pages four and five by placing the listings of organisms and associated contact times within the directions for use section of the label on page five.

6) Revise the beginning of the Directions for Use section to state: "{Select from *Kill Claims and include associated contact time.*}" Your label does not include complete directions regarding how to apply the product. Also add the following statement to the beginning of the Directions for Use section: *"Apply this product by sponge, mop, spray or immersion to wet all surfaces thoroughly."*

7) Add the following statement to the farm premise directions on page five: "...Treated surfaces must remain wet for 3 minutes (*5 minutes for Canine Parvovirus*). Immerse all..."

8) Data indicates that this product is effective against HCV and HBV with a 2 minute contact time. HIV-1 data shows a 3 minute contact time. Thus revise the directions for HBV and HCV on page five by placing "##" symbol next to the 2 minute contact time and "oo" next to the 3 minute contact time. Delete the reference to a 5 minute contact time as this time is not appropriate for any of the three organisms listed in this section.

9) Add the following statement to the "Surface Disinfection" section on page six and the "For Surface Sanitization" section on page six: *"Apply this product by sponge, mop, spray or immersion to wet all surfaces thoroughly."*

10) Delete the reference to "Sanitize" in the "For Use to Pre-Clean [Sanitize] [or Disinfect] Endoscopes Prior..." section on page six as sanitize is not an acceptable claim for medical device surfaces. Also delete the associated "10 seconds for sanitization" claim from this section.

11) Revise the Precautionary Statements to include the following expanded "Wash thoroughly..." statement as per the Label Review Manual. Revise to include: *"Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."*

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General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: Stamped Label, DER D 390328
7510P:T.Lantz:9/30/11:70144-1 accepted w comment

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EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY

Opti-Cide® 3

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

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%
Isopropanol	21.000%
Other Ingredients*	<u>78.692%</u>
Total	100.000%

Keep Out of Reach of Children

CAUTION

See back [side] panel for First Aid and additional Precautionary Statements.

EPA Reg. No. 70144-1 EPA Est. 1130-IL-1

Net Contents: _____ oz. (_____ ml)
{2 ounces through 270 gallons}



Made in the U.S.A.

{Marketing Copy}

Antibacterial

Antimicrobial

Bactericidal

Cleaner [Cleans]

Disinfectant [Disinfects] [in 2 [3 or 5 {as appropriate}] minutes]

{Insert *Use Sites*} Disinfectant and Cleaner

For use on {insert *Descriptors*}

Fungicidal

Hospital Uses

Housekeeping and In-Home Use

[Pre-Cleaning] Instrument [Device] Soak

Kills Bacteria – Viruses* – Fungi – Tuberculocide on hard, non-porous inanimate surfaces such as {insert *Descriptors*}

Kills Bacteria, Viruses*, Fungi, *Mycobacterium-tuberculosis* (var. bovis) [in 2 minutes]

~~Kills 99.9% of Bacteria [Germs]~~

● Kills 99.9% of *Staphylococcus aureus* and *Enterobacter aerogenes*

Kills MRSA

Kills H1N1 Influenza A Virus* [(formerly called "swine flu")]

Medical/Surgical/Dental/Hospital {or other descriptor} Surface and Equipment Disinfectant Cleaner

Ready-to-Use

Sanitizer** [Sanitizes**] [Hard Surfaces] [Soft Surfaces] [in 10 seconds]

Scope pre-cleaning [pre-cleaner] [and] [sanitizer] [sanitizing] [disinfection] [disinfectant]

Spot Cleaner

Spot Cleaning of {insert descriptors} Sanitizer [Disinfectant] Cleaner

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 3 - 2011

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **70144-1**

Spot Cleaning of {insert descriptors} Sanitizer [Disinfectant] Cleaner

Surface {insert descriptors} [Disinfectant] [Sanitizer] [and Cleaner]

This product is particularly effective in {at}: {insert *Use Sites*}:

Tuberculocidal [Tuberculocide check spelling]

Virucidal* [Virucide*]

~~With [Contains] Bleach [Bleach] [Bleach]~~

With [Contains] Fresh {or other appropriate descriptive term} Scent

With [Contains] Rust Inhibitor

Use where control of the hazards of cross-contamination is important [of concern].

Aids in the reduction of cross-contamination on treated surfaces.

This product [{product name}] is particularly effective for cleaning and disinfecting {insert *Descriptors*}

When used as directed this product [{product name}] effectively cleans and disinfects hard, non-porous, environmental, inanimate surfaces such as {insert *Descriptors*}

{Use Sites:}

This product is particularly effective in {at}: {insert *Use Sites*}: Acute care facilities, air transport facilities, airports, amusement parks, ambulatory care centers, ambulatory care facilities, anesthesia areas, animal/pet care facilities, animal control facilities, animal control vehicles, animal breeding facilities, animal detention facilities, animal hospitals, animal laboratories, animal research facilities, animal rescue shelters, animal shelters, animal show facilities, animal trailers, apartments, arboreta, arcades, ATM surfaces, automatic teller machine (ATM) surfaces, auto facilities, autopsy rooms, avian care facilities, avian facilities, avian units, bakeries, banks, barber shops, bathroom facilities, bathrooms, bedrooms, blood banks, blood drawing centers, blood units, body piercing salons, body service facilities, body storage facilities, botanical gardens, bowling alleys, bus facilities, bus stations, cab facilities, canine facilities, canine units, cardiac catheterization labs, cardiac catheterization laboratories, cash dispensing machines, Cat-scan labs, Cat-scan laboratories, central instrument reprocessing facilities, child care facilities, clean rooms, clinical areas, colleges, condominiums, convention facilities, correctional facilities, CS labs, CS laboratories, CT labs, CT laboratories, currency exchanges, day care centers, day care schools, day spas, delivery units, dental care facilities, dental laboratories, dental offices, detention facilities, dialysis centers, dialysis units, drug preparation facilities, drug preparation rooms, early learning centers, electrolysis facilities, emergency medical service (EMS) units, emergency rooms, endoscopy centers, endoscopy facilities, endoscopy departments, entertainment facilities, environmental services facilities, equine facilities, equine units, esthetician facilities, eye care facilities, exam rooms, examination rooms, feline facilities, feline units, fire departments, fire/rescue departments, florists, food processing facilities, foot spas, foreign currency exchange facilities, foreign currency exchanges, forestry services, funeral homes, gaming facilities, garden centers, general public facilities, GI labs, GI laboratories, golf courses, grocery stores, grammar schools, grooming facilities, grounds keeping services, gymnasiums, gyms, habitats, hair salons, health clubs, high schools, holding cells, home health care facilities, homes, hospice rooms, hospitality facilities, hospitals, hotels, household bathrooms, housekeeping rooms, hydrotherapy facilities, hydrotherapy rooms, infant care facilities, instrument reprocessing areas, intensive care units (ICUs), isolation rooms, jails, kindergartens, kitchens, labor units, laboratories, landscaping services, lasik eye centers, lawn services, learning institutions, limousine facilities, living rooms, lockup facilities, lockups, long-term care facilities, medical facilities, medical offices, medivans, MICUs, middle schools, money handling facilities, morgues, mortuary facilities, mortuaries, motels, movie theaters, MRI facilities, MRI labs, MRI laboratories, nail salons, neonatal intensive care units (NICUs), newborn nurseries, nuclear medicine facilities, nurseries, nursery schools, nursing homes, occupational therapy centers, occupational therapy facilities, operating rooms, ophthalmology centers, ophthalmology facilities, ophthalmology units, optometric offices, oral health care facilities, orthodontic offices, outpatient care facilities, outpatient facilities, outpatient surgery centers, patient care rooms, pathology rooms, pediatric units, pedicure salons, personal care service facilities, pet homes, pet motels, pet spas, pet stores, pharmacies, physical therapy centers, physical therapy facilities, plasma pheresis centers, plasma pheresis facilities, pheresis units, post-op rooms, post operative rooms, pre-op areas, pre-operation areas, pre-schools, primary care facilities, prisons, public facilities, public bathrooms, public transportation facilities, radiology rooms, reception areas, recovery rooms, recreation facilities, rehabilitation facilities, rescue departments, respiratory therapy facilities, reptile habitats,

restaurants, restroom facilities, retail stores, rodent facilities, rodent units, schools, sleeping rooms, scope reprocessing rooms, shopping malls, sick room facilities, sick rooms, skilled nursing centers, skin care facilities, skin care salons, snack shops, spas, SPD labs, SPD laboratories, tanning salons, tattoo studios, taxi facilities, taxi cab facilities, theaters, toilet facilities, train facilities, train stations, transport vehicles, transportation waiting rooms, tree services, universities, urgent care centers, urgent care facilities, veterinary hospitals, waiting rooms, weight training facilities, X-ray rooms, zoos and other similar establishments.

{Descriptors:}

Use [this product] [{product name}] to clean, disinfect and sanitize soft non-food contact surfaces or hard, non-porous inanimate surfaces such as those made of acrylic, aluminum, brass, glass, metal, plastics (polycarbonate, polypropylene, polystyrene and polyvinylchloride [(PVC)]), Plexiglas®, stainless steel, vinyl as well as coated, laminated and painted surfaces such as air evacuation transport units, air transport units, air vents, airplane fixtures, airplane interiors, ambulance interior surfaces, ambulances, amusement machine surfaces, analgesia equipment surfaces, anesthesia machines, apnea monitors, aquariums, armrests, athletic facility fixtures, ATM touch buttons, automatic teller machine (ATM) touch buttons, attendant seats, tables, backboards, balloon pumps, bank teller surfaces, bar tops, bassinets, bathing tubs, bathroom facilities, bathroom fixtures, bathroom surfaces, bathtubs, bedrails, beds, bedside devices, bedside tables, bedside stands, biohazard team equipment, biological monitoring devices, bird cage surfaces**, birthing room fixtures, bits, blood bank surfaces, blood pressure equipment, blood pressure units, bowls, breathing monitors, bridles, brushes, cabinets, cages, call buttons, cardiac monitors, cash register surfaces, cash registers, carts, central supply equipment, chainsaw blades, chairs, changing tables, chest pumps, classroom fixtures, clipper blade, clippers, cloth furniture [surfaces], coated mattresses, coated pillows, coin counter surfaces, coin dispensers, collars, colon equipment surfaces, combs, commodes, computer keyboards, computer screens, computer touch-screens, cots, counters, countertops, CPAP masks, CPAP units, CPR training devices, CPR training manikins, crash carts, cribs, CT equipment, curing lights, curtains, cuspidors, cutting boards**, decks, dental impressions, dental trays, diaper changing tables, diaper pails, dictating machines, diving equipment, diving masks, door handles, doorknobs, drinking fountain exteriors, drug preparation equipment, drug preparation hoods, dry suits, dumbbells, elevator buttons, elevator panels, emergency room stretchers, emergency medical technician units, emergency rescue squad vehicles, EMT units, embalming tables, empty whirlpool tanks, endoscope light source units, endoscope machine surfaces, endoscope machine tubing, endoscopes, endoscope surfaces, environmental patient care fixtures, equipment counters, ER stretchers, escalator handrails, exam equipment, exam lights, exam room lights, exam room surfaces, exam tables, examination equipment, examination lights, examination room lights, examination room surfaces, examination tables, face shields, faucets, finger print counters, first-aid stretchers, fish nets**, fish tank aerators**, fish tank filters**, fish tank gravel**, fish tanks**, fixtures, floors, flower pots**, food delivery carts, foot spa bowls, frequently touched surfaces, furniture, gaming machines, garbage cans, garbage compactors, garden equipment, garden storage bins, garden tools, gastroenterology equipment devices, gastroenterology equipment fixtures, glucometers, goggles, gonial lenses, grass mower blades, grooming facility surfaces, grooming tables, gym mats, hair care stations' fixtures, hair brushes, hair clippers, hair combs, hair driers, handcuffs, handrails, harnesses, hazmat team equipment, hearse interiors, helicopters, high chairs, high-touch areas, horse trailers, hospice rooms, household fixtures, Hubbard tanks, hydrotherapy units, hygiene treatment surfaces, hyperbaric chambers, IC pumps, immobilization devices, implements, incubators, infant care equipment, infant care warmers, infant changing tables, infant incubators, infant seats, infant transport incubators, infant warmers, infant warming equipment, isolettes, instrument reprocessing equipment, instrument trays, interior tubing lumens, IV poles, IV stands, kennels, kick buckets, kitchen fixtures, lab benches, lab fixtures, laboratory benches, laboratory fixtures, laryngoscopes, leashes, leather surfaces, light lens covers, light pull chains, light switches, lights, litter boxes, locker room benches, lockers, lockup facility fixtures, manicure implements, masks, mats, mattress covers, mayo stands, medication carts, micro-derma abrasion equipment, microkeratome surfaces, microscopes, monitors, MRI equipment surfaces, nail implements, nail station fixtures, nail station tables, non-critical devices, non-critical operating room lights, non-critical operating room surfaces, non-critical operating room tables, non-critical OR lights, non-critical OR surfaces, non-critical OR tables, non-food/feed contact surfaces, non-food/feed preparation surfaces, non-porous hazmat suits, non-porous plastic-covered menus, nursing station fixtures, OB/Gyne surfaces, OB/Gynecology surfaces, operating room lights, operating room surfaces, operating room tables, optical wear

(excluding contact lenses), OR lights, OR surfaces, OR tables, organ scales, oxygen hoods, oxygen units, paramedic units, patient care fixtures, patient beds, patient bedrails, patient chairs, patient lifts, patient restraints, patient transport carts, patient transport vehicles, pedicure chairs, pedicure chair tubs, pedicure implements, PEEP units, pet care surfaces, pharmacy counters, pharmacy surfaces, phototherapy lights, physician office surfaces, plastic mattress covers, play-care equipment, play mats, poker machine surfaces, pooper scoopers, prisoner benches, pulse oximeters, pumps, rails, razors, reception area fixtures, recreational devices, refrigeration units, remains bags, remote controls, reptile habitats**, reptile heat rocks**, rescue dive team equipment, rescue squad equipment, respirator ventilators, respirators, respiratory therapy equipment, restraints, resuscitators, salon fixtures, scales, scissors, scoop stretchers, scuba equipment, seats, self-contained breathing apparatus (SCUBA) equipment, shampoo bowls, sheers, shower doors, shower surfaces, showers, shower stalls, sinks, skin care equipment surfaces, sleeping mats, slit lamps, slot machines, slot machine surfaces, soap containers, soap dishes, SPD equipment, splinting devices, squad benches, stalls, stair-chairs, stethoscopes, stools, stretchers, suction devices, suction machines, suction units, supply cabinets, surgical tables, tables, tabletops, tanning beds, telemetry equipment, telephones, toilet facilities, toilets, toilet seats, toilet surfaces, toilet training equipment, tonometers, tonometer tips, tools, touch screens, toys**, trash can lids, trash cans, treatment hoods, transport vehicle interiors, transport vehicle surfaces, tree saws, tubing, turf equipment, turf equipment blades, TV remote controls, unplugged hair driers, upholstered fixtures, van fixtures, van interiors, vehicle interiors, vending machine surfaces, ventilators, veterinary operating room lights, veterinary operating room tables, video poker machines exteriors, walkers, walls, washing bowls, water bowls**, waterproof mattresses, weight machines, weight scales, weight training equipment, wet suits, wheelchairs, window sills, work stations, wrestling mats, workout machines, x-ray units and other similar items [other high-touch, non-food contact items] [other high-touch areas].

**Must be thoroughly rinsed with potable water after cleaning, disinfect and/or sanitization.

{Kill Claims:}

10-second sanitization contact time against:

Enterobacter aerogenes [ATCC 13048]

Staphylococcus aureus [ATCC 6538]

Two-minute contact time against:

Bovine Viral Diarrhea Virus* (BVDV-Surrogate Hepatitis C Virus)

Duck Hepatitis B Virus* (DHBV-Surrogate Hepatitis B Virus)

Hepatitis B Virus* (HBV)

Hepatitis C Virus* (HCV)

~~Human Simian Virus (HIV-2) (HIV-2)~~

~~Human Immunodeficiency Virus* (HIV-1) (associated with AIDS)~~

~~Influenza Virus Strain A2/Hong Kong~~

Pseudomonas aeruginosa [ATCC 15442]

Salmonella enterica [ATCC 10708]

Staphylococcus aureus [ATCC 6538]

Methicillin-Drug Resistant *Staphylococcus aureus* (MRSA) [ATCC 33591]

Mycobacterium bovis BCG (tuberculosis) (TB)

Trichophyton mentagrophytes [(ringworm)] [ATCC 9533]

Vancomycin-Resistant *Enterococcus faecalis* (VRE) [ATCC 51299]

Three-minute contact time against:

Acinetobacter baumannii [ATCC 19606]

Avian Influenza A Virus [ATCC VR-2072]

Bordetella bronchiseptica (kennel cough) [ATCC 10580]

Canine Distemper Virus* [ATCC VR-128]

Canine Para-Influenza Virus [ATCC VR-666]

Chlamydia psittaci [ATCC VR-125]

Herpes Simplex II virus

Human Immunodeficiency virus

Influenza virus, Strain A2 / Hong Kong

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Escherichia coli ESBL (*E. coli*) [ATCC BAA-196]
Feline Leukemia Virus*
Infectious Bovine *Rhinotracheitis* Virus* [ATCC VR-188]
Klebsiella pneumoniae – Carbapenem-resistant (KPC) [ATCC BAA-1705]
Listeria monocytogenes [ATCC 19111]
Murine Norovirus* Strain MNV-G
Polio I Virus* [ATCC VR-58]
Rhinovirus* [ATCC VR-286]
Rotavirus* Strain WA
Serratia marcescens [ATCC 14756]
Streptococcus equi [ATCC 33398]
Swine Influenza A (H1N1) Virus* [ATCC VR-333] (formerly known as "swine flu")

5-minute contact time against:

Canine Parvovirus*

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

{End of Marketing Copy}

{Back/Side Panel(s)}

DIRECTIONS FOR USE

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

When used as directed this product [{product name}] effectively kills the following microorganisms at room temperature [(69°F/20°C)]: {Select from *Kill Claims*}

{The following sentence is required when the Avian Influenza A kill claim appears on a spray bottle label:}

For disinfection of Avian Influenza A, use this product as a spray only for surfaces that are not conducive to treatment by immersion or excess liquid.

{The following paragraph is required (per DIS/TSS 18) when the product is for farm premises uses:}

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barn, pens, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with this product and rinse with water. Then saturate all surfaces with this product [{product name}]. Treated surfaces must remain wet for 3 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels, scrapers used in removing litter and manure. 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 waterers with soap or detergent and rinse with potable water before use.

{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 label bears HBV, HCV and/or HIV-1 kill claims:}

HBV, HCV and HIV-1 Precautions: This product [{product name}] kills 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:** Specific barrier protection items to be used when handling items soiled with blood or body fluids are

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disposable latex gloves, gowns, masks and eye coverings. **Cleaning Procedure:** Blood and body fluids must be thoroughly cleaned from surfaces/objects before disinfection. **Contact Time:** Allow the surface to remain wet for 2 [3 or 5] (as appropriate) minutes prior to wiping. **Infectious Materials Disposal:** Cleaning materials used that may contain blood/body fluids must 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 or decontaminate critical and semi-critical medical devices prior to sterilization or high-level disinfection.

{Alternate statement for product intended for non-medical uses/environments:}

This product is not for use on medical devices or medical equipment surfaces.

Surfaces

Surface Cleaning: Prior to surface disinfection, pre-clean surfaces, making sure to remove all gross filth and heavy soil, by saturating surfaces with this product [{product name}] then wipe clean using a fresh paper or cloth towel. Repeat, if necessary, until surfaces are visibly clean. Discard paper towels or launder cloth towels before reusing.

For Cleaning Walls and Floors: In a clean bucket, dilute 4 oz. of this product per gallon of warm, clean, potable water. Thoroughly damp-mop floor or wipe walls using a clean rag or sponge. Allow to air dry.

Surface Disinfection: Apply this product [{product name}] to pre-cleaned surfaces. Allow to remain wet for 2 [3 or 5] (as appropriate) minutes [at room temperature (69°F/20°C)] then wipe dry using a clean paper or cloth towel; or rinse surface using potable water and either wipe surface dry or allow to air dry. Discard paper towels or launder cloth towels before reuse.

For Surface Sanitization: Apply this product [{product name}] to pre-cleaned surfaces. Allow to remain wet for 10 seconds [at room temperature (69°F/20°C)] then wipe dry using a clean paper or cloth towel; or rinse surface using potable water and either wipe surface dry or allow to air dry. Discard paper towels or launder cloth towels before reuse.

Instruments [Devices]

For Use as a Pre-Cleaning Instrument [Device] Soak: Fill appropriately-sized container with a sufficient amount of this product to allow for complete submersion of items. Place items into solution and allow to soak for 2 minutes. Be certain to flush lumens of hollow devices with this product. Remove items and rinse. For critical and semi-critical items, follow with the appropriate cleaning and disinfection or sterilization process. Change solution as needed, i.e., when the solution becomes diluted or visibly soiled.

For Use as a Pre-Cleaning Wipe: Saturate a clean sponge, gauze wipe or cloth with this product. Thoroughly wipe item [device] [instrument] [exterior scope surface] until visibly clean. Dispose of sponge, gauze wipe or cloth.

For Use to Pre-Clean [Sanitize] [or Disinfect] 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 using a rag, towel or sponge saturated with this product until visibly clean. Using a second fresh rag, towel or sponge, re-wipe the entire exterior surface of the insertion tube and allow to remain wet for 10 seconds for sanitization [3 minutes for disinfection]. To clean the internal channels of the scope, aspirate [suction] this product through the internal channels, through the suction tubing and into the suction jar until the solution is visibly clean. Cover the scope and transport to the appropriate area for terminal reprocessing.

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For Use as a Pre-Cleaning [Instrument] [Device] Spray: Place item into a suitable container. Thoroughly spray item with this product until drenched, thoroughly rinse, then follow with the appropriate terminal cleaning and sterilization/disinfection process.

For Use as an Ultrasonic Cleaning Solution: Prepare the ultrasonic bath using a dilution ratio of 1 fl. oz. of this product with 1 quart of clean, potable water. Place items into the ultrasonic bath, activate unit and allow unit to operate until items are visibly clean. Remove items and thoroughly rinse. Proceed with appropriate disinfection process.

For Cleaning [To Clean] Hair Clippers and Electric Shears: Disconnect from the electrical supply. Hold in the downward position and apply this product directly onto the blades, making sure the solution does not drain into the housing. Wipe dry with a clean, soft cloth.

For Cleaning and Disinfecting Dental Impressions: For cleaning, apply this product until thoroughly drenched, then rinse with potable water and wipe or air dry. For disinfecting, reapply product to thoroughly wet the surfaces and allow to remain wet for 2 [3 {as appropriate}] minutes. Rinse with water and wipe or air dry.

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[For Use as a] Non-Critical Medical Item Disinfection Immersion Solution: Thoroughly pre-clean items being sure to remove all gross filth and heavy soil, then rinse and dry. Allowing for complete submersion of item(s), place pre-cleaned item(s) into an appropriate container that has been filled with this product. Flush lumens of hollow devices with this product. Allow item(s) to remain submerged for 2 [3 {as appropriate}] minutes. Remove, rinse with clean, potable water and dry. Change solution daily or when it becomes visibly soiled or discolored.

[For Use as a] Sanitizer for Hair Clipper and Electric Shear(s):** Disconnect from the electrical supply. Hold pre-cleaned item in a downward position and apply this product to thoroughly wet the blades, making sure the solution does not drain into the housing. Allow to remain wet for 10 seconds, then wipe dry with a clean, soft cloth. Lubricate blades per the manufacturer's instructions.

[For Use as a] Personal Care Instrument/Implements Sanitizer:** Immerse pre-cleaned items (such as combs, brushes, razors, manicure/pedicure tools, tweezers and scissors) in this product. Allow items to remain immersed for at least 10 seconds. When ready for use, thoroughly rinse and/or wipe dry using a clean cloth or paper towel. Change solution at least daily or when solution becomes visibly dirty or discolored.

{For use on Non-Refillable Containers with Household/Residential Use}

Storage and Disposal

Store in original container in areas inaccessible to children. Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Wrap and put in trash.

{For non-refillable containers (1 gallon to 5 gallons in capacity):}

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a cool, well-ventilated [(preferably locked)] area inaccessible to children and pets. **Pesticide Disposal:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. **Container Disposal:** Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container 1/4 full with water and reclose the container. Agitate vigorously and dispose of rinsate in accordance with Pesticide Disposal instructions. Repeat two more times. Offer for recycling if available. Puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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{For refillable bottles:}

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a cool, well-ventilated, [preferably locked] area inaccessible to children and pets. **Pesticide Disposal:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. **Container Disposal:** Refillable container. Refill this container with only the product originally supplied in this container. Do not reuse this container for any other purpose. When empty, fill the container about 10 percent full of water. Agitate vigorously and dispose of contents on site or at an approved waste disposal facility. Offer container for recycling, if available; otherwise dispose of container in trash.

{For non-refillable non-household/residential use products (greater than 5 gallons capacity):}

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in original container in a cool, well-ventilated, [preferably locked] area inaccessible to children and persons unfamiliar with its use. **Pesticide Disposal:** Wastes resulting from the use of this product must be disposed of on site, or at an approved waste disposal facility. **Container Disposal:** Non-refillable container; do not reuse or refill this container. Offer for recycling, if available. Triple rinse (or equivalent) container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

{For refillable non-household/residential use products greater than 5 gallons capacity:}

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in original container in a cool, well-ventilated, [preferably locked] area inaccessible to children and persons unfamiliar with its use. **Pesticide Disposal:** Wastes resulting from the use of this product must be disposed of on site, or at an approved waste disposal facility. **Container Disposal:** Refillable container. Refill this container with this product only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container and store for later disposal. Fill container 1/4 full with water and reclose the container. Agitate vigorously and dispose of rinsate in accordance with Pesticide Disposal instructions. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

{Per PR Notice 2007-4, a lot or batch number will appear on either the container or label of all non-refillable containers.}

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.}

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.

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 U.S.A.

Telephone: 1-888-253-2536

[Product] Order No: _____

Opti-Cide is a registered trademark of Micro-Scientific Industries, Inc.

[] Denotes alternate language

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

