

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 9, 2005 (amended Dec 12, 2005)

Sally Hayes, Agent for Oculus Scientific and Regulatory Consultants, Inc. P.O. Box 1014 Columbia City, IN. 46725

Subject:

Oculus

EPA File No. 81206-1

July 25, 2005 label amendment

Dear Ms. Hayes:

The amendment referred to above, submitted in connection with registration of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Act (PRIA) is conditionally acceptable. In summary, your request to add disinfection claims against *Staphylococcus aureus* MRSA, *Enterococcus faecalis* Vancomycin Resistant, *Acinetobacter baumanii*, and *Trichophyton mentagrophytes* is acceptable. A copy of our review and conditionally accepted label is enclosed.

The following revisions are required on your label:

- On page 6 under the "Bactericidal" section, change "...Pseudomonas aeruginosa and against Escherichia coli O157:H7..." to read "...Pseudomonas aeruginosa. Passes AOAC Use-Dilution Test against Escherichia coli O157:H7..."
- On page 7 under the "Contact Time" section, change 20°C (77°F) to read 20°C (69°F).

Please provide a copy of your revised finished label for our files. If you have questions concerning this letter, please contact Tom Luminello by telephone, (703)-308-8075 or by e-mail at luminello.tom@epa.gov.

Sincerely,

Emily H. Mitchell Acting Product Manager 32

Enclosure: EET DER

Oculus Microcyn Disinfectant (OMD)

with MicrocynTM Technology

Bactericidal Fungicidal Tuberculocidal [in 5 minutes] Virucidal[†]

Hospital Disinfectant pH Balanced Oxidized Water with Chlorine and ionic stabilizers such as H_2O_2 , ClO_2 and O_3

READY TO USE

(No Mixing, Activating or Dilution Required)

Formulated for Effective Disinfection in Households Formulated for Effective Disinfection in Hospitals ACCEPTED Formulated for Effective Disinfection in Industrial Areasomments m EPA Letter Dated: NOV - 9 2005

Hospital Disinfectant Cleaner Instrument Presoak Disinfectant Cleaner

Under the Federal Insecticide, Functions, and Rodenticiae Act as anienaed, for the pesticide, registered under EPA Reg. No.

81206-1

ACTIVE INGREDIENTS:

*68 ppm available chlorine

Sodium Hypochlorite*..... 0.00357% Hypochlorous Acid*.....0.00252% OTHER INGREDIENTS.... 99,99391% TOTAL.....100.00000%

Net Contents {Insert Contents Here}

EPA Reg. No. 81206-1

EPA Est. No. {Insert EPA Est. No. Here}

Keep Out of Reach of Children

Manufactured by: Oculus Innovative Sciences, Inc., 1129 N. McDowell Blvd., Petaluma, CA 94954

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{additional optional product claims that may be on front panel or any other panel}

Institutional Disinfectant Cleaner
Dental Disinfectant Cleaner
Veterinary Disinfectant Cleaner
Medical Disinfectant Cleaner
Surface Disinfectant Cleaner
Laboratory Disinfectant Cleaner
Household Disinfectant Cleaner
Commercial Facility Disinfectant Cleaner

Formulated for Effective Food Contact Sanitization Food Contact Sanitizer

[DESCRIPTION]

Oculus Microcyn Disinfectant (OMD) is a multi-purpose hospital disinfectant, fungicide cleaner and food contact sanitizer for use on hard non-porous inanimate surfaces. Oculus Microcyn Disinfectant (OMD) is a super-oxidized, pH-neutral, purified water-based solution. It is a broad-spectrum, ready-to-use product that is especially useful in patient care areas, households, child care facilities, health clubs, laboratories and on food contact surfaces where cross-contamination of treated surfaces can occur. Oculus Microcyn Disinfectant (OMD) will effectively disinfect hard, non-porous surfaces such as non-critical medical devices, countertops, sinks, showers, surgical tables, doorknobs and floors when used in accordance with the Directions for Use.

ACCEPTED
with COMMENTS
m EPA Letter Dated:

NOV - 9 2005

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81206-1

[FEATURES]

Fast-Acting

Broad-Spectrum Disinfectant [and Sanitizer]

No special handling or disposal requirements

Durable, stable solution with 1 year shelf life

Non-corrosive

Non-flammable

Multi-functional

No dilution or mixing required

Effective under ambient temperatures

No expensive machinery or equipment required

Kills virus[†], fungus and bacteria on hard non-porous [inanimate] surfaces and food contact areas

Ready-to-use: No dilution or mixing required

Eliminates odors: Kills odor causing bacteria and fungi while simultaneously chemically

neutralizing their odor

Kills [Effective against] [Reduces] the antibiotic resistant bacteria MRSA and VRE [MRSA] [methicillin resistant Staph. aureus] [vancomycin resistant Enterococcus faecalis] [VRE] [on hard non-porous surfaces]

Kills[Effective against][Reduces] T. mentagrophytes [(Athlete's Foot Fungus)] [Athlete's Foot Fungus] [Fungi][Mold] [on hard non-porous surfaces]

ACCEPTED
with COMMENTS
a. EPA Letter Dated:

NOV - 9 2005

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FOR USE ON HARD, NON-POROUS SURFACES IN:

Commercial:
Office Buildings,
Recreational Facilities
Restaurants And Bars
Convenience Stores
Food Processing Plants
• Food Storage Areas
Institutional Kitchens
Athletic/Exercise Facilities
Barber Shops
Dressing Rooms
Factories
Public Rest Rooms
Hair and Nail Salons
Tanning Salons
Camp Grounds
* Kennels
Pet Shops
■ Zoos
■ Laboratories
Medical Device Manufacturing Facilities
Mortuaries
■ Morgues
Animal Shelters and Kennels
Beer/wine/liquor Production Facilities
Agricultural:
■ Dairy Farms
■ Hog Farms
Poultry Farms
■ Turkey Farms
Government:
Prisons
Correctional Facilities
Fire Stations
Police Stations
į
Transportation:
■ Cars ACCEPTED
• Trucks with COMMENTS
Motorcycles m EPA Letter Dated:
Airplanes
• Trains NOV - 9 2005
Boats
Buses Federal Insecticide,
■ Campers and Rodenticide Act as
 Emergency Vehicles salier the pesticide,
• Ships reg. stered under EPA Reg. No.
• Taxis • Trailers 91206-1

Product name: Oculus Microcyn Disinfectant (OMD) 07/22/05 Page 5 of 10

DISINFECTS THE FOLLOWING HARD NON-POROUS SURFACES

Appliances Diaper Changing Tables Mirrors Stainless Steel Anesthesia Machines Doorknobs Nail Files Steamrooms **Animal Cages Drinking Fountains** Non-critical Medical Stoves Automobile Interiors Faucets Equipment and Stovetops Bathroom Fixtures Floors Devices Stretchers

Oxygen Hood Surface Surgical Beds/Tables Bathtubs Garbage Cans

Gardening Tools Physical Therapy Tables **Bed Railings** Gymnasium/Fitness Equipment Telephones **Bidets** Cabinets Equipment Plexiglas® Glazed Tile Toilet Exteriors Hair Cutter Blades Razors Cages

Refrigerator Exteriors Tubs Chairs (sealed wood Hair Dryers Hair/Nail Implements Respiratory Equipment Tweezers and metal)

Hand Rails Salon Surfaces Urinal Exteriors Computers

Walls Counters Highchairs Saunas

Workstations Cribs Litterboxes Scissors

Dental Irrigation Shampoo Bowls Metal

Equipment Surfaces Manicure Tables Showers Eyeglasses Microwave Oven Shower Doors

Desks Exteriors Sinks

SANITIZES THE FOLLOWING HARD NON-POROUS SURFACES

Glass Baby Bottles **Food Contact Surfaces** Kitchen Utensils Microwave Oven Exteriors Food/Beverage Storage Container Refrigerator Exteriors

MICROBIOCIDAL ACTIVITY

Feed Containers

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Oculus Microcyn Disinfectant (OMD) kills the following bacteria, fungi, and viruses: ACCEPTED

with COMMENTS

Salmonella choleraesuis – 10 minutes Bactericidal m EPA Letter Dated:

Staphylococcus aureus – 10 minutes Pseudomonas aeruginosa – 10 minutes NOV - 9 2005

Staphylococcus aureus MRSA 10 minutes Under the Federal Insectedde, Enterococcus faecalis VRE - 10 minutes .cc. and Rodentionae Act as Escherichia coli O157:H7 – 1 minute

. ni ule desticide, . g.....c.au izidei EPA Reg. No. Acinetobacter baumannii 10 minutes Trichophyton mentagrophytes [(Athlete's Foot Fungus)] = 10 minutes 81206 -

Fungier ... Mycobacterium tuberculosis var bovis – 5 minutes

Tuberculocidal

Sanitizer Salmonella typhi – 1 minute

HIV-1[†] - 10 minutes Virucidal

Product name: Oculus Microcyn Disinfectant (OMD) 07/22/05

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BACTERICIDAL: Passes AOAC Use-Dilution Test in 10 minutes against Salmonella choleraesuis, Staphylococcus aureus, Staphylococcus aureus MRSA, Enterococcus faecalis VRE, Acinetobacter baumannii, and Pseudomonas aeruginosa and against Escherichia coli 0157:HZ in-1 minute in the presence of 5% organic soil (serum). Passes attacher ADAC 40

FUNGICIDAL: Passes AOAC Fungicidal Activity Test in 10 minutes against Trichophyton mentagrophytes [(Athlete's Foot Fungus)].

TUBERCULOCIDAL: Passes AOAC Quantitative Tuberculocidal Test against Mycobacterium tuberculosis, var. bovis in 5 minutes in the presence of 5% organic soil (serum).

VIRUCIDAL: Passes ASTM Virucidal Test against HIV-I in 10 minutes in the presence of 5% organic soil (serum).

SANITIZER: Equivalent to 100ppm available chlorine in an AOAC Available Chlorine Test in 1 minute against Salmonella typhi. ACCEPTED with COMMENTS m EPA Letter Dated:

ODOR CONTROL

Oculus Microcyn Disinfectant (OMD) eliminates many odors by killing odor-causing bacteria Under the Federal Insecticide, and fungi while simultaneously chemically neutralizing their odors. - . sic.e. and Rodonticide Act as

DIRECTIONS FOR USE

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

To Disinfect:

Precleaning is required. [Preclean surfaces.] Apply Oculus Microcyn Disinfectant (OMD) to hard non-porous surfaces with a cloth, mop, sponge, or coarse sprayer. Wet all surfaces thoroughly. Allow surface to remain wet for 10 minutes. Wipe surface using a paper or cloth towel or allow to air dry prior to use. Discard towel. The solution must be discarded after each use. For tuberculocidal activity Oculus Microcyn Disinfectant (OMD) is effective in 5 minutes at 20°C in the presence of 5% organic soil.

To Sanitize:

Precleaning is required. [Preclean surfaces.] Apply Oculus Microcyn Disinfectant (OMD) to hard non-porous surfaces with a cloth, mop, sponge, or coarse sprayer. Wet all surfaces thoroughly. Allow surface to remain wet for 1 minute then air dry.

For dishes, glassware and utensils: Wash and rinse. After washing soak for at least one minute in Oculus Microcyn Disinfectant (OMD), drain and air dry.

[†]KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED, ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS in health care settings 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 likely to be soiled with blood / body

Note: Bracketed [] information is optional text. Text separated by a comma (,) denotes-and/or-options. {Bracketed Text} is for administrative purposes only and will not appear on the printed label.

fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type I (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

Personal Protection: Disposable protective gloves, gowns, face masks, or eye coverings as appropriate must be worn during all cleaning of blood / body fluids and during decontamination procedures.

Cleaning Procedures: Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of disinfectant.

before application of disinfectant.

Contact Time: HIV-1 (AIDS virus) is inactivated in 10 minutes at 20°C (7%°F) (room temperature).

Disposal of Infectious Materials: Blood / body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP/ KENNELS DISINFECTION DIRECTIONS:

For cleaning and disinfecting the following hard nonporous surfaces: equipment not to be used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Saturate surfaces with Oculus Microcyn Disinfectant (OMD) for a period of 10 minutes. Immerse handling and restraining equipment such as leashes, muzzles, halters or topesED Ventilate buildings and other closed spaces. Do not house animals or employequipmentalitis m EPA Letter Dated: treatment has been absorbed, set or dried.

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For Farms, and Poultry Houses:

Under the Federal Insecticide, Fundada, and Romenticido Act us

- 1. Remove all animals and feeds from premises, vehicles, coops, crates, and enclosure sucide.

 2. Remove all litter, manure and droppings from floors, walls and surfaces of barns, pens, chutes
- and other facilities occupied or traversed by animals.
- 3. Empty all troughs, racks, and other feeding and watering appliances.
- 4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5. Saturate surfaces with Oculus Microcyn Disinfectant (OMD) for a period of 10 minutes.
- 6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
- 7. Ventilate buildings, coops, vehicles, and other closed spaces. Do not house livestock, poultry or employ equipment until treatment has been absorbed, set, or dried.
- 8. Thoroughly scrub treated feed racks, troughs, mangers, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

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FOR PRECLEANING INSTRUMENTS, EQUIPMENT AND SURFACES PRIOR TO DISINFECTION:

Apply Oculus Microcyn Disinfectant (OMD) directly to surface. Allow to remain wet for 30 seconds.

Wipe surface using a paper or cloth towel to dry. Discard towel.

FOR DISINFECTING NON-CRITICAL INSTRUMENTS AND EQUIPMENT SURFACES:

Thoroughly preclean surfaces prior to disinfection with Oculus Microcyn Disinfectant (OMD). Apply Oculus Microcyn Disinfectant (OMD) directly to precleaned surface, thoroughly wetting area to be disinfected. Allow surface to remain wet for 10 minutes at room temperature (69°F/20°C).

For tuberculocidal activity, Oculus Microcyn Disinfectant (OMD) is effective in 5 minutes at room temperature in the presence of 5% organic soil. Oculus Microcyn Disinfectant (OMD) is effective against E.coli O157:H7 in 1 minute at 20°C in the presence of 5% organic soil. Wipe surface using a paper or cloth towel or allow to air dry. Discard towel.

FOR PRECLEANING AND DISINFECTING MEDICAL INSTRUMENTS:

FOR USE AS A PRECLEANING IMMERSION SOLUTION:

Fill appropriate size container with a sufficient amount of Oculus Microcyn Disinfectant (OMD) as to allow for complete submersion of instruments. Place instruments into Oculus Microcyn Disinfectant (OMD) solution, cover and allow to soak for 10 minutes at 20°C (69°F/20°C). Remove and rinse instruments. Follow with appropriate disinfection process. When the solution becomes diluted or visibly soiled, change solution.

FOR USE AS A PRECLEANING SPRAY:

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Place instruments into suitable container. Spray Oculus Microcyn Disinfectant (OMD) ontocide, instruments so as to thoroughly saturate all surfaces. Allow to remain well for 30 secondanticide Act as Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. When the solution becomes diluted or visibly soiled, change solution.

FOR USE AS AN ULTRASONIC CLEANING SOLUTION:

Thoroughly pre-rinse instruments under Oculus Microcyn Disinfectant (OMD) or running water to remove visible gross debris. Fill ultrasonic unit with Oculus Microcyn Disinfectant (OMD) to a level which allows complete submersion of instrument. Immerse instruments into solution and activate ultrasonic unit for 10 minutes. Remove instruments. Follow with appropriate disinfection process. When the solution becomes diluted or visibly soiled, change solution.

FOR USE AS A MANUAL CLEANER:

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Thoroughly pre-rinse instruments under Oculus Microcyn Disinfectant (OMD) or running water to remove visible gross debris. Fill container with Oculus Microcyn Disinfectant (OMD) to a level which allows complete submersion of instrument. Immerse instruments into solution and scrub for 30 seconds. Allow instruments to remain submerged for 10 minutes. Remove instruments. Follow with appropriate disinfection process. When the solution becomes diluted or visibly soiled, change solution.

FOR DISINFECTING NON-CRITICAL, PRECLEANED MEDICAL INSTRUMENTS:

Instruments must be thoroughly precleaned to remove excess organic debris, rinsed and rough dried. (Clean and rinse lumens of hollow instruments before filling with solution or before immersion.) Using either a soaking tray or an ultrasonic unit, immerse instruments into Oculus Microcyn Disinfectant (OMD) solution for 10 minutes. For tuberculocidal activity, allow 5 minutes submersion at room temperature. Remove and rinse instruments. Wipe surface using a paper or cloth towel to dry prior to use. Discard towel. The solution must be discarded after each use.

Note: Critical and semi-critical devices must be followed by an appropriate terminal sterilization/high-level disinfection process.

{Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, the following statements must be used}

This product is not to be used as a terminal sterilant / 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 normally sterile areas of the body. This product may be used to preclean critical or semi-critical devices prior to sterilization or high-level disinfection.

FOR CLEANING HAIR CLIPPERS ELECTRIC SHEARS/RAZORS:

While clippers/shears are running, hold it in the downward position and spray Oculus Microcyn Disinfectant (OMD) directly onto the blades two or three times so as to thoroughly wet the blades. (Avoid spraying on the clippers/shears case or dripping into the clipper housing.) Allow to remain wet for 10 minutes. Wipe with a clean, soft cloth. Lubricate as per clippers/shears manufacturer's instructions.

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FOR CLEANING SALON IMPLEMENTS, SHEARS AND BARBER IMPLEMENTS:

Spray implement/shears to thoroughly wet with Oculus Microcyn Disinfectant (OMD) solution. Wipe away visible debris using a soft bristle brush or cloth. Immerse precleaned implement/shears into a container of Oculus Microcyn Disinfectant (OMD) for 10 minutes. Remove implement/shears and wipe dry. No rinsing is necessary. When the solution becomes diluted or visibly soiled, change solution.

NOTE: Upon opening this container, record the date on the container. If the product is transferred to spray bottles or other containers, record the same date on the secondary container. HPDE, PET or glass containers are recommended for secondary container storage. Oculus Microcyn Disinfectant (OMD) may be used for up to 30 days after opening. After 30 days, discard any remaining product in accordance with local, state and federal regulations. OPEN DATE:

PHYSICAL OR CHEMICAL HAZARDS

Product contains a strong oxidizer. Always flush drain before and after use. Do not use or mix with other household chemicals such as toilet bowl cleaners, rust removers, acids, or products containing ammonia. To do so will release hazardous, irritating gases. Prolonged contact with metal may cause pitting or discoloration.

Environmental Hazard

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This pesticide is toxic to fish and aquatic organisms

{For containers one gallon or less}

STORAGE AND DISPOSAL

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

Oculus Microcyn Disinfectant (OMD) should be stored in its original sealed container at room temperature, away from direct sunlight and heat to avoid deterioration.

Do not reuse empty container; dispose of in trash.

{For 2 ½ gallon containers}

STORAGE AND DISPOSAL

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

Oculus Microcyn Disinfectant (OMD) should be stored in its original sealed container at room temperature, away from direct sunlight and heat to avoid deterioration.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Triple rinse (or equivalent). Do not reuse empty container. Dispose of in GASE BF SHEr for recycling.

with CCIMMENTS

made Letter Dated:

NOV - 9 2005

Under the Federal Insecticide, Function a and Rodenticide Act as

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