



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue, NW
Washington, D.C. 20004

EPA Reg. Number:

81206-1

Date of Issuance:

OCT 21 2004

Term of Issuance:

Conditional

Name of Pesticide Product:

Oculus Microcyn
Disinfectant

NOTICE OF PESTICIDE:

 Reregistration
 X Registration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Ocutus Innovative Sciences, Inc..
1129 N. McDowell Blvd.
Petaluma, CA 94954

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Make the following label changes:
 - a. Revise the EPA Registration Number to read, "EPA Reg. No. 81206-1"
 - b. Throughout the label except for "HIV" delete the word "Decontaminant".
 - c. On page 2, under the heading **DESCRIPTION**, add "of treated surfaces" after the word "cross-contamination".

Signature of Approving Official:

Emily H. Mitchell
Emily H. Mitchell, Acting Product Manager

Date:

10-21-04

- d. On page 4, under the heading **DISINFECTS THE FOLLOWING HARD NON-POROUS SURFACES**, delete the following claims: Bath Mats, Cervical Collars, Hairbrushes and Combs, Laminates, Neck Braces, and Plastics are not hard non-porous surfaces.
- e. On page 4, under the heading **DISINFECTS THE FOLLOWING HARD NON-POROUS SURFACES**, specify the following claims: Dental Irrigation Equipment (what part of the dental equipment), Hair Cutters, and Oxygen Hoods.
- f. On page 4, Under the heading **SANITIZES THE FOLLOWING HARD NON-POROUS SURFACES** make the following changes
 - Change the word “Baby Bottles” to read: “Glass Baby Bottles”.
 - Delete the claim “Pacifiers”.
 - Change the word “Microwave Ovens” to read: “Microwave Oven Exteriors”.
 - Change the word “Refrigerators” to read: “Refrigerator Exteriors”.
- g. On page 4, under the heading **MICROBIOCIDAL ACTIVITY** change “Escherichia coli 0157H” to read: “Escherichia coli 0157:H7”.
- h. Place the “Environmental Hazards Statement” on the label to read:

ENVIRONMENTAL HAZARDS STATEMENT

This pesticide is toxic to fish and aquatic organisms.
- i. Place the **PHYSICAL OR CHEMICAL HAZARDS STATEMENT** on your label.

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

A stamped copy of the label is enclosed for your records.

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Oculus Microcyn Disinfectant (OMD)

with Microcyn™ Technology

ACCEPTED
with COMMENTS
EPA Letter Dated:

Bactericidal
Tuberculocidal in 5 minutes
Virucidal†

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
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Hospital-Grade 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
Formulated for Effective Disinfection in Industrial Areas

Hospital Disinfectant ~~XXXXXXXXXX~~ Cleaner
Instrument Presoak
Disinfectant ~~XXXXXXXXXX~~ Cleaner

ACTIVE INGREDIENTS:

Sodium Hypochlorite..... 0.00357%

Hypochlorous Acid.....0.00252%

OTHER INGREDIENTS... 99.99391%

TOTAL.....100.00000%

Net Contents {Insert Contents Here}

EPA Reg. No. {Insert EPA Reg. No. Here}

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

Keep Out of Reach of Children

CAUTION

See back/side panel for additional precautionary statements.

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 hospital-grade multi-purpose disinfectant/ 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 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.

FEATURES

Fast-Acting
 Broad-Spectrum Disinfectant
 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

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FOR USE ON HARD, NON-POROUS SURFACES IN:

Homes: <ul style="list-style-type: none"> ▪ Bathrooms ▪ Kitchens ▪ Laundry Rooms ▪ Bedrooms ▪ Family Rooms ▪ Porches ▪ Patios ▪ Garages ▪ Closets ▪ Pet Animal Quarters Medical: <ul style="list-style-type: none"> ▪ Hospitals ▪ Surgical Rooms ▪ Nursing Homes ▪ Dental Offices ▪ Emergency Rooms ▪ Clinics ▪ Isolation Areas and Quarantine Rooms ▪ Neonatal Units ▪ Ophthalmic and Optometric Facilities ▪ Eye Surgical Centers ▪ Critical and Intensive Care Units Government: <ul style="list-style-type: none"> ▪ Military Quarters ▪ Barracks ▪ Postal Offices ▪ Customs/Immigration Facilities ▪ Political Offices and Environments 	Commercial: <ul style="list-style-type: none"> ▪ Office Buildings, ▪ Recreational Facilities ▪ Restaurants And Bars ▪ Convenience Stores ▪ Food Processing Plants ▪ Food Storage Areas ▪ Institutional Kitchens ▪ Athletic/Exercise Facilities ▪ Barber Shops ▪ Prisons ▪ Correctional Facilities ▪ Dressing Rooms ▪ Factories ▪ Public Rest Rooms ▪ Hair and Nail Salons ▪ Tanning Salons ▪ Camp Grounds ▪ Kennels ▪ Pet Shops ▪ Zoos ▪ Fire Stations ▪ Police Stations ▪ Laboratories ▪ Medical Device Manufacturing Facilities ▪ Mortuaries ▪ Morgues ▪ Animal Shelters and Kennels ▪ Beer/wine/liquor Production Facilities
Accommodations: <ul style="list-style-type: none"> ▪ Hotels ▪ Motels ▪ Mobile Homes ▪ Condos ▪ Bed & Breakfasts 	Agricultural: <ul style="list-style-type: none"> ▪ Dairy Farms ▪ Hog Farms ▪ Poultry Farms ▪ Turkey Farms
Educational: <ul style="list-style-type: none"> ▪ Pre-Schools ▪ Elementary Schools ▪ Grade Schools ▪ High Schools ▪ Colleges ▪ Universities ▪ Playgrounds ▪ Day Care Centers ▪ Cafeterias ▪ Gymnasiums ▪ Locker Rooms ▪ Shower & Bath Area 	Transportation: <ul style="list-style-type: none"> ▪ Cars ▪ Trucks ▪ Motorcycles ▪ Airplanes ▪ Trains ▪ Boats ▪ Buses ▪ Campers ▪ Emergency Vehicles ▪ Ships ▪ Taxis ▪ Trailers <p style="text-align: right;"> ACCEPTED with COMMENTS EPA Letter Dated: OCT 21 2004 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide, registered under EPA Reg. No. 81206-1 </p>

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DISINFECTS THE FOLLOWING HARD NON-POROUS SURFACES

Appliances	Desks	Microwave Oven	Showers
Anesthesia Machines	Diaper Changing Tables	Exteriors	Shower Doors
Animal Cages	Doorknobs	Mirrors	Sinks
Automobile Interiors	Drinking Fountains	Nail Files	Stainless Steel
Bathroom Fixtures	Faucets	Oxygen Hoods	Steamrooms
Barriers	Floors	Refrigerators	Stove
Bathtubs	Garbage Cans	Non-critical Medical	Stovetops
Bed Railings	Gardening Tools	Equipment and	Stretchers
Bidets	Gymnasium/Fitness	Devices	Surgical Beds/Tables
Cabinets	Equipment	Physical Therapy	Tables
Cages	Equipment	Equipment	Telephones
Chairs	Hair Cutters	Equipment	Glazed Tile
Chairs (sealed wood and metal)	Hair Dryers	Plexiglas®	Toilet Exteriors
Computes	Hair/Nail Implements	Razors	Tubs
Counters	Hand Rails	Refrigerator Exteriors	Tweezers
Cribs	Highchairs	Respiratory Equipment	Urinal Exteriors
Dental Irrigation	Highchairs	Salon Surfaces	Walls
Equipment	Litterboxes	Saunas	Workstations
Eyeglasses	Metal	Scissors	
	Manicure Tables	Shampoo Bowls	

SANITIZES THE FOLLOWING HARD NON-POROUS SURFACES

Baby Bottles
Kitchen Utensils
Food/Beverage Storage Container
Feed Containers

Food Contact Surfaces
~~Food Contact Surfaces~~
Microwave Ovens
Refrigerators

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MICROBIOCIDAL ACTIVITY

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

- Escherichia coli O157H*
- HIV-1†***
- Mycobacterium tuberculosis var bovis **
- Pseudomonas aeruginosa ***
- Salmonella choleraesuis ***
- Salmonella typhi *
- Staphylococcus aureus***

*Effective at one-minute contact time

**Effective at five-minute contact time in the presence of 5% soil

***Effective at ten-minute contact time

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

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BACTERICIDAL: Passes AOAC Use-Dilution Test in 10 minutes against *Salmonella choleraesuis*, *Staphylococcus aureus* and *Pseudomonas aeruginosa* and against *Escherichia coli* 0157:H7 in 1 minute in the presence of 5% organic soil (serum).

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 minute against *Salmonella typhi*.

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ODOR CONTROL

OCT 21 2004

Oculus Microcyn Disinfectant (OMD) eliminates many odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors.

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

DIRECTIONS FOR USE

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

To Disinfect:

For heavily soiled areas, a precleaning is required. 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 20C in the presence of 5% organic soil.

To Sanitize:

For heavily soiled areas, a precleaning is required. 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 fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type I (HIV 1) (associated with AIDS).

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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.

Contact Time: HIV-1 (AIDS virus) is inactivated after a contact time of 10 minutes at 20°C (77°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 ropes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

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EPA Letter Dated:**

For Farms, and Poultry Houses:

1. Remove all animals and feeds from premises, vehicles, coops, crates, and enclosures.
2. Remove all litter, manure and droppings from floors, walls and surfaces of buildings, pens, 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.
7. 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 AND DISINFECTING MEDICAL SURFACES:**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 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 DECONTAMINANT SOLUTION:**

Fill appropriate size container with a sufficient amount of Oculus Microcyn Disinfectant (OMD) 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.

ACCEPTED

with COMMENTS

EPA Letter Dated:

October 2, 2004

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

FOR USE AS A PRECLEANING DECONTAMINANT SPRAY:

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

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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

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activate ultrasonic unit for 10 minutes. Remove instruments. When the solution becomes diluted or visibly soiled, change solution.

FOR USE AS A MANUAL CLEANER:

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

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Under the Federal Insecticide,
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limited use pesticide,
registered under EPA Reg. No.

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.

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.

PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
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. • Call a poison control center or doctor for treatment advice.
CONTACT NUMBER	
For emergency medical advice, call your local poison control center or a doctor. Have the product container or label with you when seeking medical advice or treatment.	

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.

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