

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

April 6, 2021

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Brian Hogan Agent Aquaox LLC 17355 Hamlin Blvd. Loxahatchee, FL 33470

Subject: Notification per PRN 98-10 – Add Special Instructions for HIV

Product Name: Aquaox Disinfectant 525 EPA Registration Number: 93392-2 Application Date: January 27, 2021

Action Case Number/Decision Number: 571263

Dear Mr. Hogan:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

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) lists 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 Assurance.

If you have any questions, you may contact Wanda Henson at (703) 308-6345 or via email at henson.wanda@epa.gov

Sincerely,

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

Aquaox Disinfectant 525

Hypochlorous Acid Solution Generated Electrochemically from Sodium Chloride

ACTIVE INGREDIENT:

 Hypochlorous Acid
 0.0525%

 OTHER INGREDIENTS:
 99.9475%

 TOTAL:
 100.0000%

Contains > 525ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN

EPA Reg. No. 93392-2

Est. No. xxxxx-xx-xxx

Manufactured by:

AQUAOX LLC

17355 Hamlin Boulevard Loxahatchee, Florida 33470 Phone No.: 800-790-7520 Email: info@aquaox.net

Aquaox Disinfectant 525 must be used within 30 days after production OR Product must be tested with chlorine test kit provided by Aquaox. DO NOT USE PRODUCT when Chlorine concentration is below 473ppm.

DATE PRODUCED:					
Container size: 1 gallon.	5gallon, 30 gallon,	55 gallon.	275 gallon.	330 gallon.	660 gallor

NOTIFICATION

93392-2

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

04/06/2021

Aquaox Disinfectant 525 is a Hypochlorous Acid solution produced by passing an aqueous saline solution (brine) through 1 or more electrolytic cells. The current within the electrolytic cell(s) splits the sodium chloride compound into two separate fluids. One fluid is Hypochlorous Acid, a powerful oxidizing agent exhibiting antimicrobial properties.

Aquaox Disinfectant 525 is produced at a near neutral pH, (approximately pH 6.5) where the predominant antimicrobial agent is Hypochlorous Acid, an efficient and efficacious species of chlorine. Hypochlorous Acid kills bacteria, fungi, molds, viruses and spores.

Aquaox Disinfectant 525 properties are closely controlled by controlling the voltage and the current to the electrolytic cell(s), brine conductivity, temperature and flow rate through the cells as well the pH of the Hypochlorous Acid generated in the cell(s).

Aquaox Disinfectant 525 freezes at 32°F and boils at 212°F. It is a colorless and aqueous solution with a slight chlorine or ozone odor.

After production, **Aquaox Disinfectant 525** must be stored in a closed plastic container in a cool and dark area away from direct sunlight.

Aquaox Disinfectant 525 is intended to be used soon after being produced.

Optional Marketing Statements:

- a cost-effective disinfecting solution;
- produced with low energy and low costs from water and salt;
- produced in a single-stage process by a simple electrolytic cell;
- produced for use in medical, institutional, industrial and commercial applications and
- produced with a controlled pH and controlled concentration of Free Available Chlorine (FAC).
- Directions Spray cleaned surfaces and allow to air dry
- No wiping needed
- See attached insert for directions for use, storage and disposal statements.
- Aquaox Disinfectant 525 leaves no residue.
- Aquaox Disinfectant 525 is made from salt and water.
- Aquaox Disinfectant 525 will eventually degrade back to salt and water.

PRECAUTIONARY STATEMENTS

Physical or Chemical Hazards: **Aquaox Disinfectant 525** is not compatible with other chemicals such as acids and hydrogen peroxide.

DIRECTIONS FOR USE

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

Hard, Non-Porous Surface Disinfection

To [Clean and] Disinfect [and Deodorize] Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply [Wipe, Spray or Dip] **Aquaox Disinfectant** to hard, non-porous surfaces with a cloth, wipe, mop, sprayer, sponge or a spray applicator. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Do not use on utensils, glasses or dishes.

Follow the instructions below when applying with a spray applicator for hard, non-porous surface disinfection: (1) Remove disinfectant liquid at or over 1-week-old from the liquid storage tank; (2) Fill the empty liquid storage tank with fresh **Aquaox Disinfectant 525** liquid; (3) Turn on the power on the main electrical switch; (4) Pull out the spray gun and point towards the target area to be sprayed; (5) Press the sprayer button and start spraying at a recommended distance of between $1\frac{1}{2} - 4$ ft. from the target area; (6) When applying to a large, hard, non-porous surface, use a recommended motion of a 3-ft., side-by-side motion. Allow an overlap of 50% of the sprayed area when spraying from the top to the bottom, and an overlap of 10% when spraying adjacent areas; (7) Sprayed surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Do not use on utensils, glasses or dishes.

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, 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 <u>pre-clean or decontaminate</u> critical or semi-critical devices prior to sterilization or high-level disinfection.

Pathogen	Strain	Contact Time
Pseudomonas aeruginosa	ATCC 15442	10 minutes
Staphylococcus aureus	ATCC 6538	10 minutes
Staphylococcus aureus (HA-MRSA)	ATCC 33591	10 minutes
Swine Influenza Virus (H1N1)	ATCC VR-333	10 minutes
Escherichia coli (NDM)	ATCC BAA-2469	10 minutes
Vancomydin Resistant Enterococcus feacalis (VRE)	ATCC 700221	10 minutes
Human Immunodeficiency Virus Type 1 (HIV-1)	Mn; ZeptoMetrix #0810027CF	10 minutes
Mycobacterium bovis (BCG)	ATCC #35734	10 minutes
Salmonella enterica	ATCC 10708	10 minutes

Special Instructions for Using Aquaox Disinfectant to Clean and Decontaminate Against HIV on Hard, Non-Porous Environmental Surfaces Soiled with Blood/Body Fluids.

This product kills HIV-1 on pre-cleaned hard, non-porous environmental surfaces previously soiled with blood/body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces with blood or body fluids, and in which the surfaces likely to be soiled with blood or body fluid can be associated with the potential for transmission of Human Immunodeficiency Virus type 1 (HIV-1) (associated with AIDS).

Personal Protection: When handling items soiled with blood or body fluids, use appropriate barrier protection such as disposable latex gloves, gowns, masks, and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and other objects before applying this product.

Contact Time: Apply Aquaox Disinfectant to area to be treated. Let stand for 10 minutes. Cleaning materials used that may contain feces/wastes should be disposed of immediately in accordance with local regulations for infectious materials disposal.

Disposal of Infectious Material: Blood and other body fluids must be autoclaved and disposed of according to local requirements for infectious waste disposal.

Claims

- + Broad spectrum disinfectant
- + One-step cleaner/disinfectant when disinfection directions are followed
- + Aids in the reduction of cross-contamination between treated surfaces
- + This Disinfection Process assures proper strength, product effectiveness and standardizes technique
- + Formulated for bacteria fighting
- + Bactericide or Bactericidal
- + Bathroom disinfectant
- + + Nursery disinfectant
- + Athletic facility disinfectant
- + Cleans and disinfects sites listed on Tables 1 4 below
- + Cleans and disinfects hard, non-porous surfaces
- + Cleans, deodorizes and disinfects
- + Deodorizes by Killing Odor-Causing Bacteria
- + Disinfecting formula
- + Disinfects and deodorizes by killing bacteria and their odors
- + Disinfects hard, non-porous surfaces on sites listed on Tables 1 4 below
- + Easy and convenient disinfecting on sites listed on Tables 1 4 below
- + Easy one-step cleaning and disinfecting when disinfection directions are followed
- + Effective against or Kills organisms listed on Table on Page 2above
- + Effective against or Kills a wide range of bacteria including Staphylococcus aureus, MRSA, Salmonella enterica, and Pseudomonas aeruginosa
- + Effectively disinfects hard, non-porous, environmental surfaces
- + Eliminates odors at their source; bacteria
- + Eliminates or Reduces odors caused by bacteria
- + Fight(s) and/or Kill(s) and/or Effective against Salmonella enterica
- + Fight(s) and/or Kill(s) and/or Effective against Staphylococcus aureus and MRSA
- + Fight(s) and/or Kill(s) and/or Effective against Pseudomonas aeruginosa
- + Fight(s) and/or Stops and/or Prevent(s) cross-contamination on hard, non-porous surfaces on sites listed on Tables 1 4
- + Kills bacteria
- + Kills many common bacteria
- + Kills odor-causing bacteria
- + Kills or Effective against bacteria
- + Multi-purpose disinfectant
- + One-step cleaner and disinfectant when disinfection directions are followed
- + One-step disinfectant cleaner (when disinfection directions are followed) designed for general cleaning and disinfecting hard, non-porous environmental surfaces in health care facilities or and sites listed on Tables 1 4 below.
- + Pseudomonocidal
- + Ready-to-use hospital disinfectant
- + Staphylocidal
- + The answer to your disinfecting needs
- + The quick and/or easy and/or convenient way to disinfect
- + This product controls cross-contamination on most hard, non-porous surfaces
- + This product meets AOAC efficacy testing requirements or standards for hospital disinfection
- + Use in public or common places where bacteria may be of concern on hard, non-porous surfaces
- + Use where control of the hazards of cross-contamination between treated hard non-porous surfaces is of Prime importance
- + Kills or Effective against H1N1 Swine Influenza virus

GENERAL CLAIMS

+ Convenient

+ Easy to Handle

+ For General Use

+ For use on Bathroom Surfaces

+ For use on Nursery Surfaces

+ For use in Athletic Facilities

+ Suitable for HOSPITAL USE

+ For use on Athletic Equipment

+ Will not Harm Surfaces listed on Tables 1 - 4

+ Will not Harm Hard, Non-Porous Inanimate Environmental Surfaces

+ Will not Harm Titanium-Coated, Medical Grade Stainless Steel

TABLE ONE: Medical Environments

USE SITES

- + Ambulances or Emergency Medical Transport Vehicles
- + Anesthesia Rooms or Areas
- + Assisted Living or Full Care Nursing Homes
- + CAT Laboratories
- + Central Service Areas
- + Central Supply Rooms or Areas Critical Care Units or CCUs
- + Dialysis Clinics
- + Emergency Rooms or RS (Registered Sanitarian) Health Care Settings or Facilities
- + Home Health Care Settings
- + Hospitals
- + Intensive Care Units or ICU Laboratories
- + Medical or Physician's or Doctor's Offices Newborn or Neonatal Nurseries
- + Medical Clinics
- + Medical Facilities
- + Nursing or Nurses' Stations
- + Orthopedics
- + Outpatient Clinics
- + Patient Restrooms
- + Patient Rooms
- + Pediatric Examination Rooms or Areas
- + Pharmacies
- + Physical Therapy Rooms or Areas
- + Radiology or X-Ray Rooms or Areas
- + Surgery Rooms or Operating Rooms or ORs

SURFACES (Applicable to Surface Materials listed on Page 9)

- + Bed pans
- + Exam or Examination Table
- + External surfaces of Medical Equipment or Medical Equipment surfaces
- + External surfaces of Ultrasound Transducers
- + Gurneys
- + Hard, Non-Porous Environmental Hospital or Medical Surfaces
- + Hospital or Patient Bed Railings or Linings or Frames
- + IV Poles
- + Patient Chairs
- + Plastic Mattress Covers
- + Reception Counters or Desks or Areas
- + Stretchers
- + Wash Basins
- + Wheelchairs

TABLE TWO: Dental Environment

USE SITES

- + Dental Operatory rooms
- + Dental or Dentist's Offices

SURFACES (Applicable to Surface Materials listed on Page 9)

- + Dental Countertops
- + Dental Operatory Surfaces
- + Dentist or Dental Chairs
- + Hard, Non-Porous Environmental Dental Surfaces
- + Light Lens Covers
- + Reception Counters or Desks or Areas

TABLE THREE: Veterinary Environments

Animal Premises: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the floors, walls and surfaces of barns, pens, stalls, 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 soap and/or detergent and rinse with water.

Apply **Aquaox Disinfectant** and saturate surfaces with solution for 10 minutes. 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.

After application, ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

USE SITES

- + Animal or Pet Grooming Facilities Kennels
- + Animal Housing Facilities
- + Animal Life Science Laboratories
- + Livestock and/or Swine and/or Poultry Facilities
- + Pet Areas
- + Pet Shops or Stores
- + Small Animal Facilities
- + Veterinary or Animal Hospitals
- + Veterinary Clinics or Facilities
- + Veterinary Offices

SURFACES (Applicable to Surface Materials listed on Page 9)

- + Animal Equipment Automatic Feeders
- + Cages
- + External surfaces of Veterinary Equipment
- + Feed Racks
- + Fountains
- + Hard, Non-Porous Environmental Veterinary Surfaces
- + Pens
- + Reception Counters or Desks or Stall Areas
- + Troughs
- + Veterinary Care Surfaces
- + Watering Appliances

TABLE FOUR: Miscellaneous / General Environments

USE SITES

- + Airplanes
- + Blood Banks
- + Boats
- + Bowling Alleys
- + Chillers
- + Churches
- + Colleges
- + Correctional Facilities
- + Cruise Lines
- + Day Care Centers
- + Dormitories
- + Factories
- + Funeral Homes
- + Grocery Stores
- + Gymnasiums or Gyms
- + Health Club Facilities
- + Hotels
- + Industrial Facilities
- + Laundromats
- + Laundry Rooms Locker Rooms
- + Manufacturing Facilities
- + Manufacturing Plants or Facilities
- + Military Installations
- + Motels
- + Preschool Facilities
- + Public Areas
- + Recreational Centers or Facilities
- + Restrooms or Restroom Areas
- + School Buses
- + Schools
- + Shelters
- + Shower Rooms
- + Storage Rooms or Areas
- + Supermarkets
- + Trains
- + Universities
- + Wineries
- + Yachts

SURFACES (Applicable to Surface Materials listed on Page 9)

- + Bath Tubs
- + Bathroom Fixtures
- + Behind and under Counters
- + Behind and under Sinks
- + Booster Chairs
- + Cabinets Ceilings
- + Cellular or Wireless or Mobile or Digital Phones
- + Chairs
- + Computer Keyboards
- + Computer Monitors
- + Counters or Countertops
- + Cribs
- + Desks
- + Diaper or Infant Changing Tables
- + Diaper Pails
- + Dictating Equipment Surfaces
- + Doorknobs
- + Exterior or external Toilet Surfaces
- + Exterior or external Urinal Surfaces
- + Faucets
- + Floors
- + Garbage or Trash Cans
- + Grocery store or Supermarket Carts
- + Hampers
- + Hand Railings
- + Headsets
- + Highchairs
- + Lamps
- + Linoleum
- + Playpens
- + Shelves
- + Showers or Shower Stalls
- + Sinks
- + Stall Doors
- + Tables
- + Telephones
- + Tiled Walls
- + Toilet Rims
- + Toilet Seats
- + Towel Dispensers
- + Toys
- + Vanity tops or Vanities
- + Other Telecommunications Equipment Surfaces

SURFACE MATERIALS

- + Baked enamel
- + Chrome
- + Common Hard, Non-Porous Household or Environmental Surfaces
- + Formica
- + Glass
- + Glazed Ceramic Tile
- + Glazed Porcelain
- + Glazed Porcelain Enamel
- + Laminated Surfaces
- + Plastic Laminate
- + Similar Hard, Non-Porous Surfaces except those excluded by the Label
- + Stainless Steel
- + Synthetic Marble
- + Vinyl Tile

Not Recommended For Use On - or - Avoid Contact With

- + Aluminum Brass
- + Chipped Enamel
- + Clear Plastic
- + Clothes
- + Copper
- + Fabrics
- + Gold
- + Natural Marble
- + Natural Rubber
- + Painted Surfaces
- + Paper Surfaces
- + Sealed Granite
- + Silver
- + Unfinished Wood
- + Wood

STORAGE AND DISPOSAL

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

For Industrial and Commercial Use Packages:

Pesticide Storage: Store in a closed dark plastic container in a cool, dry area away from heat and sunlight. Do not store near easily oxidizable materials, acids and reducers. In case of spill, isolate container (if possible) and flood area with water to dissolve all material before discarding this container in trash.

Emergency Handling: In case of contamination or decomposition. Do not reseal container. Isolate in open, well-ventilated area. Flood with large amounts of water. Cool unopened containers in vicinity by water spray.

Pesticide Disposal: Pesticide wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environment Control Agency, or the Hazardous Waste Representative at the EPA Regional Office for guidance.

Small Packages (5 gallons or less):

Container Handling: Nonrefillable rigid container. Do not reuse or refill this container. Triple-rinse container (or equivalent) promptly after emptying. Triple-rinse as follows: Empty the remaining contents into the application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Full the container ¼ with water and recap. Shake for 10 seconds. Pour rinsate contents into the application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure 2 more times. Then offer for recycling or reconditioning if available or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay clear of smoke.

Container Handling: Refillable container. Refill this container with Aquaox Disinfectant only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller. Cleaning the container before final disposal is the responsibility of the person disposing the container. To clean the container before final disposal, empty the remaining contents into the application equipment or a mix tank. Agitate vigorously or recirculate water with the pump for 2 minutes. Dispose of rinsate as pesticide waste. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by procedures allowed by state and local authorities.

Large Packages (Greater than 5 Gallons)

Container Handling: Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ 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."