

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 6, 2019

Kevin Kutcel, Agent Aquaox LLC 17355 Hamlin Blvd. Loxahatchee, FL 33470

Subject: Notification per PRN 98-10 – Additional container sizes, optional language and hard,

non-porous surfaces of cpap medical equipment

Product Name: Aquaox Disinfectant 275 EPA Registration Number: 93392-1 Application Date: December 19, 2018

Decision Number: 548467

Dear Mr. Kutcel:

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) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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

## **Highlighted**

## **Aquaox Disinfectant 275**

# Hypochlorous Acid Solution Generated Electrochemically from Sodium Chloride

ACTIVE INGREDIENT:

 Hypochlorous Acid
 0.0275%

 OTHER INGREDIENTS:
 99.9725%

 TOTAL:
 100.0000%

**Contains > 275ppm Free Available Chlorine (FAC)** 

# KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Label for Precautionary Statements

EPA Reg. No. 93392-1

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 275 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 248ppm.

D A T E	PRODUC	ED.
VAIC	PRUDUC	ED.

**Container size:** 2 oz., 3.4 oz., 4 oz., 8 oz., 16 oz, 1 gallon, 5 gallon, 30 gallon, 55 gallon, 275 gallon, 330 gallon, 660 gallon

#### NOTIFICATION

93392-1

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:

05/06/2019

**Aquaox Disinfectant 275** 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 275** 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 275** 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 as the pH of the Hypochlorous Acid generated in the cell(s).

**Aquaox Disinfectant 275** 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 275** must be stored in a closed plastic container in a cool and dark area away from direct sunlight.

Aquaox Disinfectant 275 is intended to be used soon after being produced.

**Optional Marketing Statements:** 

- Directions Spray cleaned surfaces and allow to air dry
- No wiping needed
- See attached insert for precautionary statements, directions for use, storage and disposal 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).
- Aquaox Disinfectant 275 leaves no residue.
- Aquaox Disinfectant 275 is made from salt and water.
- Aquaox Disinfectant 275 will eventually degrade back to salt and water.

#### 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.

(OPTIONAL - 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 275** 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 do 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 critical or semi-critical devices prior to sterilization or high-level disinfection.</u>

Pathogen	Strain	Contact Time
Pseudomonas aeruginosa	ATCC 15442	10 minutes
Staphylococcus aureus	ATCC 6538	10 minutes
Swine Influenza Virus (H1N1)	ATCC VR-333	10 minutes
Salmonella enterica	ATCC 10708	10 minutes

### **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 Site(s) 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
- + Eliminates or Reduces Odors caused by Bacteria
- + Eliminates odors at their source; bacteria
- + Disinfects Hard, Non-Porous Surfaces on Site(s) on Tables 1-4 below
- + Easy and Convenient Disinfecting on Site(s) on Tables 1-4 below
- + Easy One-Step Cleaning and Disinfecting when Disinfection Directions are followed
- + Effective against or Kills Organism(s) mentioned in Table on Page 2 above
- + Effective against or Kills H1N1 Swine Influenza virus
- + Effectively Disinfects Hard, Non-Porous, Environmental Surfaces
- + Fight(s) and/or Kill(s) and/or Effective against Salmonella enterica
- + Fight(s) and/or Kill(s) and/or Effective against Staphylococcus aureus
- + 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 Tables 1–4 below
- + Kills Odor-Causing Bacteria mentioned in Table on Page 2 above
- + Kills or Effective against Bacteria mentioned in Table on Page 2 above
- + Multi-Purpose Disinfectant
- + One-Step Cleaner and Disinfectant when Disinfection Directions are followed
- + One-Step Cleaner and Disinfectant (when Disinfections Direction are followed) designed for General Cleaning and Disinfecting Hard, Non-Porous Environmental Surfaces in Health Care Facilities and on Sites listed on Tables 1–4 below
- + Pseudomonocidal
- + Staphylocidal
- + Ready-to-Use Hospital Disinfectant
- + The Answer to your Disinfecting Needs
- + The 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 Importance

#### **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
- + cpap medical equipment

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

#### **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 Areas Stalls
- + 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)

- + Bathroom Fixtures
- + Bath Tubs
- + 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
- + Stainless Steel
- + Synthetic Marble
- + Vinyl Tile
- + Similar Hard, Non-Porous Surfaces except those excluded by the label

#### 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: Non-refillable 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 ½ 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."

### PRECAUTIONARY STATEMENTS

Physical or Chemical Hazards: Aquaox Disinfectant 275 is not compatible with other chemicals such as acids and hydrogen peroxide.

# Hazards to Humans and Domestic Animals **CAUTION**

Causes moderate eye irritation. Avoid contact with eyes. When handling the product, wear safety glasses or goggles. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

## **FIRST AID**

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may also contact the National Pesticide Information Center (NPIC) 1-800-858-7378 for emergency medical treatment information.

# If in eyes

- 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.