

#### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

1677-277

Date of Issuance:

9/22/22

Term of Issuance:

EPA Reg. Number:

Unconditional

Name of Pesticide Product:

Bioquell Hydrogen Peroxide Sterilant-AQ

Name and Address of Registrant (include ZIP Code):

Shannon Emerson Ecolab, Inc. 1 Ecolab Place St. Paul, MN 55102

Electronic Transmittal: shannon.emerson@ecolab.com

NOTICE OF PESTICIDE:

X Registration

\_\_\_\_ Reregistration (under FIFRA, as amended)

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials 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 under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

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 unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/registration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	Date:
Hoather a Hamie	9/22/22
Heather Garvie, Senior Regulatory Advisor	
Regulatory Management Branch II, Antimicrobials Division	
(7510P)	

EPA Form 8570-6

- 2. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 1677-277."
- 3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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, FIFRA section 12(a)(1)(B). 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 these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

Basic CSF dated 07/20/2022

If you have any questions, please contact Luisa C. Samalot-Freire by phone at (202)-566-0609, or via email at samalot.luisa@epa.gov

Enclosure

### **Bioquell Hydrogen Peroxide Sterilant-AQ**

[Hydrogen Peroxide Vapor-AQ] [HPV-AQ]

Bioquell Hydrogen Peroxide Sterilant-AQ is for use as a sterilant in conjunction with Bioquell Hydrogen Peroxide Vapor (HPV) generating equipment.

EPA Registration No1677-XXX EPA Est.	No
For Industrial Use Only	ACCEPTED
Not for human consumption or household use	09/22/2022
ACTIVE INGREDIENT:	Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 1677-277
Hydrogen Peroxide	35%
OTHER INGREDIENTS:	<u>65%</u>
TOTAL:	100%

# DANGER

[Note to Reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label.]

#### PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

**DANGER**: Corrosive, causes eye and skin damage. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling. Do not breathe vapor or spray mist. Do not enter an enclosed area without proper respiratory protection. If concentrations in excess of the OSHA PEL TWA for hydrogen peroxide are expected, NIOSH approved (TC19C) full face supplied air respirators must be worn. If the concentrations are unknown or could exceed the NIOSH IDLH of 75 PPM, then either NIOSH approved (TC-13F) Self- Contained Breathing Apparatus (SCBA) or supplied air respirators with escape bottles must be worn.

#### **FIRST AID**

**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. Call a poison control center or doctor for treatment advice.

**If on skin or clothing**: 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.

**If inhaled**: 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. Call a poison control center or doctor for further treatment advice.

**If swallowed**: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

#### PHYSICAL AND CHEMICAL HAZARDS:

Strong oxidizing agent. Mix only with water. Bioquell Hydrogen Peroxide Sterilant-AQ is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate or promote combustion of other materials.

#### **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Any solution released from the system should be diluted with water and tested for residuals to ensure that there is less than 3 ppm peroxygen remaining.

(Note to reviewer: language in parenthesis is optional. Any claim not approved by CDPR will include the statement "Use not approved in the state of California")

#### **DIRECTIONS FOR USE**

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

Bioquell Hydrogen Peroxide Sterilant-AQ is a sterilant for use in conjunction with Bioquell Hydrogen Peroxide Vapor (HPV) generating equipment.

#### [for container sizes 500 mL or larger]

The following directions are to be followed when using the Bioquell HPV equipment: The hydrogen peroxide vapor is intended for use as a sterilant in treating enclosures up to 3500 cubic feet (validated) or greater (non-validated). Use this product for sterilization as instructed in the Bioquell Use Manual. This product may not be used on food-contact surfaces unless followed by a potable water rinse. When used as a sterilant in greenhouses or growing rooms, remove all plants and soil prior to application.

#### For Enclosures up to 35 cubic feet

- 1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
- 2. Connect the Bioquell HPV generator and add Bioquell Hydrogen Peroxide Sterilant-AQ according to the Use Manual instructions. Seal the enclosure to be sterilized.
- 3. Apply Bioquell Hydrogen Peroxide Sterilant-AQ at an injection rate of 3.1 g/minute for 55 minutes.
- 4. Allow vapor to remain for a minimum of 3 hours.
- 5. Aerate the chamber using the Bioquell HPV generator until hydrogen peroxide vapor is at or below 1.0 ppm. See the Bioquell Use Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

#### For Enclosures Greater than 35 Cubic Feet to a Maximum of 3500 Cubic Feet

(Multiple 500 mL containers required for volumes greater than 35 cubic feet – refer to the table in item 3 below.)

- 1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
- 2. Connect the Bioquell HPV generator and add Bioquell Hydrogen Peroxide Sterilant-AQ according to the Use Manual instructions. Seal the enclosure to be sterilized.
- 3. Apply Bioquell Hydrogen Peroxide Sterilant-AQ at an injection rate of 10 g/minute for 2.5 hours.

Volume to be treated	Bioquell Hydrogen Peroxide Sterilant- AQ required	Number of 500ml containers required	Number of 1000ml containers required
Up to 35 cubic feet	170.5g	1	1
36-3500 cubic feet	1500g	3	2

4. Allow vapor to remain for a minimum of 15 minutes.

5. Aerate the chamber using the Bioquell HPV generator until hydrogen peroxide vapor is at or below 1.0 ppm. See the Bioquell Use Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

#### [for 150 mL containers only]

The following directions are to be followed when using the rapid gassing HPV generator, the Bioquell QUBE. The hydrogen peroxide vapor is intended for use as a sterilant in treating enclosures up to 37 cubic feet. Use this product for sterilization as instructed in the Bioquell Use Manual.

This product may not be used on food-contact surfaces unless followed by a potable water rinse.

#### For Enclosures Up to 16 Cubic Feet

- 1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
- 2. Add Bioquell Hydrogen Peroxide Sterilant-AQ according to the Use Manual instructions.
- 3. Apply Bioquell Hydrogen Peroxide Sterilant-AQ at an injection rate of 6 g/minute until 26g has been injected.
- 4. Allow vapor to remain for a minimum of 10 minutes.
- 5. Aerate the chamber using hydrogen peroxide vapor is at or below 1.0 ppm. See the Bioquell Use Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

#### For Enclosures Greater than 16 Cubic Feet to a Maximum of 37 Cubic Feet

- 1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
- 2. Add Bioquell Hydrogen Peroxide Sterilant-AQ according to the Use Manual instructions.
- 3. Apply Bioquell Hydrogen Peroxide Sterilant-AQ at an injection rate of 4 g/minute until 120g has been injected.
- 4. Allow vapor to remain for a minimum of 70 minutes.
- 5. Aerate the chamber using hydrogen peroxide vapor is at or below 1.0 ppm. See the Bioquell Use Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

#### [Emerging Viral Pathogens Claim – Hard, porous and non-porous surfaces]

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- -Enveloped Viruses
- -Large Non-Enveloped Viruses
- -Small Non-Enveloped Viruses

For an emerging viral pathogen that is	following the sterilant directions for use
a/an	in
	conjunction with Bioquell Hydrogen
Enveloped virus	Peroxide
Large non-enveloped virus	Vapor (HPV) generating equipment. Use
Small non-enveloped virus	this
·	product for sterilization as instructed in the
	Bioquell Use Manual according to the size
	of the space to be treated.

Bioquell Hydrogen Peroxide Sterilant-AQ has demonstrated effectiveness as a sterilant which is defined in 40 CFR 158.2203 as "a substance, or mixture of substances, that destroys or eliminates all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses". Thus, it is expected to be effective against viruses similar to [name of emerging virus] on hard, [porous and/or non-porous surfaces]. Therefore, Bioquell Hydrogen Peroxide Sterilant-AQ can be used against [name of emerging virus] when used in accordance with the directions for use as a sterilant on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. As a sterilant, Bioquell Hydrogen Peroxide Sterilant-AQ is expected to kill similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use as a sterilant on [hard, porous/nonporous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

**Note**: This product may not be used to sterilize medical devices.

In all applications, always prepare a new solution daily to ensure effectiveness. Do not reuse solutions. Dispose of any unused solution.

#### STORAGE AND DISPOSAL

PESTICIDE STORAGE: NEVER RETURN BIOQUELL HYDROGEN PEROXIDE STERILANT-AQ TO THE ORIGINAL CONTAINER AFTER IT HAS BEEN REMOVED.

Avoid all contaminants, especially dirt, caustic, reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of a decomposition, isolate container, douse container with cool water and dilute Bioquell Hydrogen Peroxide Sterilant-AQ with large volumes of water.

Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store this product in a cool and dry area. Do not store on wooden pallets.

#### PROCEDURE FOR LEAK OR SPILL

Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares, or spark producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

**PESTICIDE DISPOSAL:** If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements.

Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal.

Bioquell Hydrogen Peroxide Sterilant-AQ, which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

#### **CONTAINER HANDLING AND DISPOSAL**

Nonrefillable containers less than 5 gallons. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

This product may be patented | Ce produit peut être breveté | Este producto puede ser patentado: www.ecolab.com/patents

FOR INDUSTRIAL USE

STRONG OXIDIZING AGENT

EPA Reg. No. 1677-XXX

EPA Est.: 86703-PA-2, 86703-GBR-1, 1677-CA-2 (R), 1677-GA-1 (M), 1677-IL-2 (J)

Superscript refers to first letter of date code

(Manufactured)(Distributed) by: Ecolab Inc. 1 Ecolab Place St. Paul, MN 55102 Net Contents:

58 oz. (1, 715 mls)

96 oz. (2,839 mls)

55 U.S. Gals. (208.2 L) 300 U.S. Gals. (1134 L) - tote (Made in United States of America) (Made in USA)

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(Si no puede leer en inglés, pregunte a su supervisor sobre las instrucciones de uso apropiadas antes de trabajar con este producto.)

## FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE: 1-800-328-0026 OUTSIDE NORTH AMERICA, CALL 1-651-222-5352

For more information see Safety Data Sheet

#### **UN2014**

Hydrogen peroxide, aqueous solution, with not less than 20 percent but not more than 40 percent hydrogen peroxide.