



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

EPA Reg. Number:

68959-15

Date of Issuance:

12/7/22

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

STERI-PEROX® 6%WIPE

Name and Address of Registrant (include ZIP Code):

Heather Bjornson-Lam
Veltek Associates, Inc.
15 Lee Boulevard
Malvern, Pennsylvania 19355
Electronic Transmittal: heather.bjornson@sterile.com

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 conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

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

Signature of Approving Official:

Steven Snyderman, Team Leader/Product Manager, Team 33
Regulatory Management Branch II
Antimicrobial Division, OPP

Date:

12/7/22

2. You are required to comply with the data requirements described in the DCI identified below:

a. Hydrogen Peroxide - GDCI-000595-1127

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

4. Make the following label changes before you release the product for shipment:

- Revise the EPA Registration Number to read, "EPA Reg. No. 68959-15."

5. Submit one copy of the 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 you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 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. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated September 20, 2022

If you have any questions, please contact Zebora Johnson by phone at (202) 566-0730, or via email at johnson.zeboraj@epa.gov.

Enclosure: Accepted Label

[FRONT PANEL]

STERI-PEROX® 6% WIPE

WFI Formula

For Use in Cleanrooms and Controlled Areas

Hard Surface Disinfectant

[Formulated with USP Water for Injection Quality Water (0.25 EU/mL)]

(Aseptically Filtered at 0.2 µm) (Sterile)

Active Ingredients:

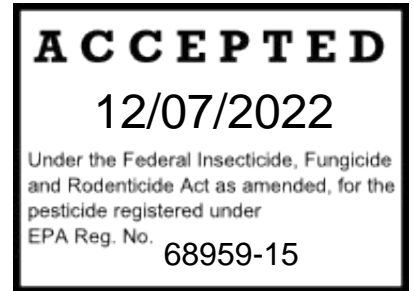
Hydrogen Peroxide CAS# 7722-84-1.....6.4%

Other Ingredients:

*Water93.6%

Total:.....100.0%

*USP Water for Injection Quality Water



KEEP OUT OF REACH OF CHILDREN

CAUTION

{Note to reviewer: The following reference statements available for various packaging scenarios.}

[See [side] [other] [back] [case label] [panel] [and/or] [package insert] for [first aid] [precautionary statements] [directions for use] [additional precautions] [and] additional product information].]

[Refer to the primary case label for [additional] precautionary statements, directions for use, and additional product information]

[Peel [here] [back] for [Spanish and] additional information]

[See container for lot number and storage expiration date]

	{Lot Label Sticker}	
Reorder {xxxxxxxxxxxx}		{QR Code}
Lot: {xxxxxxx}		
EXP. {dd-MM-YYYY}		
Net Contents: {XXX (Individually Packaged) Wipes, Size, Weight}		

EPA Reg. No.: 68959-XX

EPA Est. No.: For EPA Est. No. see the final character of the lot #: L = 68959 –PA-01, C = 68959-PA-03, T = 68959-PA-02

Patents: www.sterile.com/patents

Manufactured by:
 Veltek Associates, Inc.
 15 Lee Blvd.
 Malvern, PA 19355-1234
 Tel. (610) 644-8335

Red dot indicates Sterile {will not appear on non-sterile packages} Rev. MM#/YY ●{code}

(Made in USA) **VAI** {corporate logo}

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 five 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.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Move person to fresh air. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person.
<p>Have the product container or label with you when calling the Poison Control Center or doctor or going to treatment. For general information on product use, etc., call the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday – Friday, 8:00 am – 12:00 pm Pacific Time; email: npic@ace.orst.edu; or website: http://npic.orst.edu/. You may also contact the Poison Control Center at 1-800-222-1222 for emergency medical information.</p>	

EMERGENCIES: In the case of emergency call: 1-866-928-0789 (toll free) or 1-215-207-0061 (Americas), +52 55 5004 8763 (México)

[BACK / SIDE PANELS]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes or clothing. Wear appropriate protective eyewear such as goggles or face shield, protective clothing and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco or using the toilet. Remove and wash clothing contaminated before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PHYSICAL AND CHEMICAL HAZARDS: Strong oxidizing agent. Keep away from combustible materials. Do not mix this product with other chemicals, organic substances, or other cleaners. Incompatible with acids, alcohols, alkali, powdered metals, metal salts, reactive chemicals, organic materials and reducing agents.

DIRECTIONS FOR USE

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

*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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.*

LOCATIONS OF USE: Cleanrooms and controlled areas such as those in health care institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. Use on hard non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, Corian™, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel.

STERI-PEROX 6% WIPE are an effective hard surface disinfectant against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC#6538) in 10 minutes.

To Disinfect Hard Nonporous Surfaces:

Pre-clean all surfaces or pre-clean with STERI-PEROX 6% WIPE and dispose.

Using fresh STERI-PEROX 6% WIPE, thoroughly wet surface to disinfect. Use as many wipes as needed to ensure the treated surface remains visibly wet for 10 minutes. Allow surface to air dry, or after 10 minutes, wipe dry if needed.

Multi Pack

Open Package. Pull out wipes as needed and reseal. When not in use keep sealed to prevent moisture loss. (Peel (and) (or) Reseal Here).

Individual Wrapped Pack

Tear open packet. Unfold.

Storage and Disposal

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

Pesticide Storage: Store in original container in a cool, well-ventilated area. Do not store near heat or open flame.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate from container is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your state Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal:

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

Wipes Disposal:

Nonreusable one-time use container. Discard used and unused wipes in trash. Do not flush wipes down toilet.

Optional Label Claims:

Disinfectant
Hard Surface Disinfectant
Removes Residues (from) (disinfection)
Leaves (Low) (No) Residue
Ready to Use
Ideal for cleaning and disinfecting hard, non-porous surfaces
May be used daily
Meets USP<797> standards

{Note: To appear as label end panel for customer use on containers: convenience item.}

User Information
Date Opened/Operator: <input type="text"/>
Expiration Date: <input type="text"/>
Area: <input type="text"/>