



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 3, 2018

Heather Bjornson-Lam
Regulatory Consultant
Veltek Associates, Inc.
15 Lee Blvd.
Malvern, PA 19355

Subject: PRIA Label Amendment – Revised to Update First Aid and Precautionary Statement
Product Name: Steri-Perox 6%
EPA Registration Number: 68959-10
Application Date: 07/24/2018
Decision Number: 542955

Dear Ms. Bjornson-Lam:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,



Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Approved label



{Front Panel}

STERI-PEROX® 6%

For Use in Clean Rooms and Controlled Areas

Hard Surface Sanitizer

(Aseptically Filtered at 0.2 µm) (Sterile)

Active Ingredients:

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

Other Ingredients:

*Water CAS# 7732-18-5.....93.6%

Total**100.0%**

*USP Water for Injection Quality Water



KEEP OUT OF REACH OF CHILDREN

CAUTION



(Optional GHS Symbol)

(Note to reviewer: Include for Customers who require visual hazard symbols)

{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 mL /L) on Container or on Case (XX/CASE, Container size (yyy))}		

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

After opening use within 60 days.

US and Foreign Patents www.sterile.com/patents



EPA Reg. No.: 68959-10
EPA Est. No.: 68959-PA-1

Manufactured by:
Veltek Associates, Inc.
15 Lee Blvd., Malvern PA 19355 – 1234 USA
Tel: 610-644-8335
www.sterile.com

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

{End of Front Panel}

{Side/Back Panel}

**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 goggles or safety glasses, long-sleeved shirt and long pants, waterproof gloves, and shoes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

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.

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 Swallowed:

Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a Poison Control Center or doctor. Do not give anything to an unconscious person.



If Inhaled:

Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

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

EMERGENCIES: For Spill/Exposure/Poison Control Emergency Response Service from the USA in English, French and Spanish (and 23 other languages) call CARECHEM24 toll free at 866-928-0789.

DIRECTIONS FOR USE

Read the label before using.

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

STERI-PEROX® 6% is ready to use. Do not dilute.

For Sterilization (Sporicidal Treatment) of Manufacturing Filling and Packaging Equipment in Aseptic Processes or general surfaces in Healthcare Institutions

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.

(SPORICIDAL) ((AND) (STERILANT) TREATMENT PROCEDURE:

Prior to use of STERI-PEROX® 6%, remove gross soil from surfaces, then wash with a recommended detergent solution, followed by a thorough water rinse.

To apply, thoroughly wet or completely immerse the surface to be treated; coarse spray, flood, or soak surfaces. The surface must be kept wet for the entire contact time listed below. The following time and temperature relationship is required:

At 68° - 77°F (20° - 25°C) expose for 6 hours.



After exposure, allow surfaces to drain thoroughly and air dry, or if desired, wipe dry after exposure time using sterilized cloth. Product contact and food contact surfaces must be rinsed with sterile water. Used product should not be returned to the original container.

Storage and Disposal

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

Storage: Store in original container in a cool dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood area with large quantities of water.

Disposal: Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer. Follow Federal/Provincial/State regulations and Local/Municipal ordinances when disposing of this product. Improper disposal of excess product, spray mixture or rinsate is a violation of Federal/Provincial/State Laws. If these wastes cannot be disposed of by use according to label instructions, contact your Federal/Provincial/State or Local/Municipal environmental control agency for guidance.

Container Handling: *(Note to reviewer: This product is not dilutable.)*

Non-refillable container. Do not reuse or refill this container to hold materials other than this product. [(For containers equal to or less than 5 gallons) Offer container for recycling if available and dispose of in a sanitary landfill, or by incineration.] or [(For containers greater than 5 gallons) Offer container for recycling if available, or reconditioning if appropriate, or dispose of in a sanitary landfill, or by incineration.].

{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"/>