



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Antimicrobials Division (7510C)  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460

EPA Reg. Number:  
68959-3

Date of Issuance:  
AUG - 9 2010

Term of Issuance:

Unconditional

Name of Pesticide Product:

STER-AHOL Aerosol

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Velteq Associates, Inc  
15 Lee Blvd  
Malvern, PA 19355

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration 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/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

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 (OPP Decision No. D-426579) is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
  - a. Revise the "EPA Registration Symbol to read, "EPA Reg. No. 68959-3".
  - b. "Physical and Chemical Hazards" statements on page 2 are limited to hazards associated with the flammability, explosive potential, and associated precautions to a product's chemical or physical nature. Therefore, move the first statement in this

Signature of Approving Official:

*Jacqueline McFarlane*  
Jacqueline McFarlane, Product Manager (Team 34)  
Regulatory Management Branch  
Antimicrobials Division (7510P)

Date:

AUG - 9 2010

section to the Precautionary Statements.

c. EPA has regulatory responsibility for antimicrobial products used to disinfect noncritical devices and instruments, medical equipment surfaces, and environmental premises/surfaces. Examples of medical equipment surfaces are knobs, levers, handles, outside portions of hemodialysis machines, x-ray machines, and dental units. Floors, walls, counters, and bathroom surfaces are considered to be environmental surfaces. Any product label that states or implies the use of a product as a general disinfectant on medical devices or medical equipment surfaces must have PR Notice 94-4 MOU language. The MOU is also required when surfaces are unqualified surfaces are listed on the label; such as, stainless steel, chrome, or metal surfaces. These surfaces could possibly be associated with bed frames, wheelchairs, bedpans, or exterior surfaces of hemodialysis unit. Therefore, the following language must be added below the "Disinfection" directions:

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 devices prior to sterilization of high-level disinfection.

d. Revise the second "DIRECTIONS FOR USE" heading on page 2 to read "To Disinfect." Also, revise the 4<sup>th</sup> statement to read "Pre-Clean all surfaces prior to disinfecting" since efficacy data was not generated with organic soil.

e. Since efficacy data was submitted to support non-food contact sanitizing claims, you must add appropriate directions to support the claim. Therefore, add the following:

**To Sanitize:** Use this product wearing personal protection such as goggles and gloves. Use adequate ventilation and spray away from eyes and face. Preclean all surfaces prior to disinfecting. Hold can upright 6-12 inches from surface. Thoroughly wet surface for a minimum of 5 minutes. Allow surface to air dry, or after 5 minutes wipe dry with sterilized cloth, wiper, if needed.

f. Revise the "Disposal" subheading to read "Pesticide Disposal." Also, the statements must be revised to be in agreement with the product's signal word by stating "Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility."

g. Revise the 1<sup>st</sup> and 2<sup>nd</sup> claims on page 4 by deleting the phrase, "in the presence of fetal bovine serum organic load" since the submitted efficacy data was generated in the absence of an organic soil.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

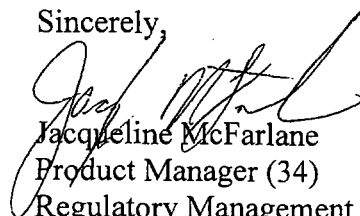
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3. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 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. Should you have any questions regarding this letter, please contact Jacqueline Campbell-McFarlane at (703) 308-6416.

Sincerely,



Jacqueline McFarlane  
Product Manager (34)  
Regulatory Management Branch  
Antimicrobials Division (7510P)

Enclosure: Stamped Label  
Efficacy Data Evaluation  
Chemistry Data Evaluation  
Acute Toxicology Data Evaluation

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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[Alternate Brand Name: STER-AHOL™ INVERTESPRAY]

# STER-AHOL™ Aerosol

**WFI Formula**

**[Gamma Irradiated]**

**For Use in Sterile Pharmaceutical Clean Rooms**

**Hard Surface Disinfectant and Sanitizer**

**Active Ingredients:**

USP Ethyl Alcohol CAS# 64-17-5.....63.3%

**Other Ingredients:**.....36.7%

**Total:**.....100.0%

\*This product contains >1% methyl alcohol

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION – FLAMMABLE - EXPLOSIVE**

Keep away from heat or open flame.

Contents under pressure

Store at room temperature below 48.8°C (120°F)

See other panel for first aid and additional precautions  
See container for lot number and storage expiration date

**EPA Reg. No.:** 68959-G

**EPA Est. No.:** 68959-PA-001

**Manufactured by:**

Veltek Associates, Inc.

15 Lee Blvd.

Malvern, PA 19355-1234

Net Contents: (XXX oz or gallons)

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated:**

**AUG - 9 2010**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. **68959-3**

FIRST AID	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>

**PRECAUTIONARY STATEMENTS**

**Not for personal use. Not for use on or around food.**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION:** Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

**PHYSICAL AND CHEMICAL HAZARDS:** This product may be irritating to the eyes, skin, gastrointestinal tract and respiratory system. Flammable liquid and vapor. Vapor may cause flash fire. Contents under pressure. Keep away from heat, sparks, direct sunlight, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 48.8°C (120° F) may cause bursting.

**PERSONAL PROTECTIVE EQUIPMENT:** Wear eye protection goggles or face shield. Wear gloves. Use supplied air respirators if levels exceed OSHA PEL (1000 ppm, 1900 mg/m<sup>3</sup> TWA).

**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.

**USE:** Disinfects and sanitizes biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. May be used to disinfect hard, inanimate surfaces in cleanrooms and controlled areas, aseptic filling and gowning rooms, general manufacturing areas, or on machinery, tools, tables, counters, laminar flow benches, floors, walls, carts, shelves and glass. It is compatible with most hard surface materials.

**DIRECTIONS FOR USE:** Use this product while wearing personal protection such as eye protection and gloves. Use with adequate ventilation and spray away from eyes and face. STER-AHOL™ Aerosol is ready to use. Do not dilute. Pre-clean surface or item of heavy soil or gross filth before application. Hold can upright 6-12 inches from surface. Thoroughly wet surface with STER-AHOL™ Aerosol and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth, wiper, if needed.

For Use on hard, non-porous environmental surfaces (made from: stainless steel, glass, Corian™, laminate flooring, aluminum, pvc, mild steel, polypropylene), in isolators, cleanrooms, sterile and controlled areas, gowning rooms and on process lines, gloves, work surfaces, tools and equipment.

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### Storage and Disposal

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

**Storage:** Store in the original container in a dry cool place below 48.8°C (120° F).

**Disposal:** Pesticide wastes are toxic. Follow Federal or 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/State Laws. If these wastes cannot be disposed of by use according to label instructions, contact your Federal/State or Local/Municipal environmental control agency for guidance. Never place unused product down any indoor or outdoor drain.

**Container Disposal:** Non-refillable container. Do not reuse or refill this container. Do not puncture container and do not incinerate container. Offer for recycling, or dispose of in a sanitary landfill.

**FIRST RESPONDERS** – In Case of Spill: Contact CHEMTREC: 1-800-424-9300

{Note to Veltek: The following information goes on the container}

Lot number/ Batch Code: XXXXX

EXPIRY: day/MONTH/year. Once opened use within XXX

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**Optional Label Claims:**

STER-AHOL™ Aerosol is bactericidal. The results of AOAC Efficacy Tests show that STER-AHOL is an effective hard surface disinfectant against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC#6538), and *Salmonella enterica* (ATCC#10708) in the presence of fetal bovine serum organic load in 10 minutes.

STER-AHOL™ Aerosol is an effective sanitizer on inanimate, non-food contact surfaces against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella pneumoniae* (ATCC#4352) in the presence of fetal bovine serum organic load in 5 minutes.

STER-AHOL™ Aerosol (This product) is sterilized by gamma irradiation for use in controlled or aseptic or sterile areas

STER-AHOL™ Aerosol (This product) is sterilized for aseptic use

STER-AHOL™ Aerosol (This product) is sterilized by gamma irradiation