

68959-1

01/29/2010

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U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:  
68959-1

Date of Issuance:  
JAN 29 2010

Term of Issuance: **Conditional**

Name of Pesticide Product:

STER-AHOL

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 19355-1234

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-419404) is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit acute toxicology six-pack data (acute oral, acute dermal, acute inhalation, primary eye irritation, primary skin irritation, and dermal sensitization) generated in accordance OPPTS Harmonized Test Guidelines 870.1000 thru 870.2600 by January 29, 2011. In the interim, the Agency is accepting the signal word and precautionary statements supporting category II language based on the primary eye irritation classification on similar product registrations because we believe this data will confirm the toxicity category II classification.

Signature of Approving Official:

Jacqueline Campbell-McFarlane, Acting Product Manager Team-34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Date:

JAN 29 2010

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. 68959-1"".
- b. This product's toxicology profile is:

Acute Oral	I	V
Acute Dermal		III
Acute Inhalation		III
Primary Eye Irritation		II
Primary Skin Irritation		IV
Dermal Sensitization		Non-sensitizer

i.) The "First Aid" Statements must be organized such that the most severe routes of exposure, as demonstrated by the toxicity classification. Therefore, reorganize the statement to read "If in eyes, If inhaled, If on skin or clothing, If swallowed."

ii.) Revise the "Precautionary Statements" to by stating:

WARNING. Causes substantial but temporary eye injury. Harmful if absorbed through the skin or inhaled. Do not get in eyes, skin, or on clothing. Avoid breathing spray mist or vapor. Wear goggles or safety glasses and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

c. "Physical and Chemical Hazards" statements are limited to hazards associated with the flammability, explosive potential, and associated precautions to the product's chemical or physical nature. Therefore, delete the first three statements in this section because they are addressed in the "Precautionary Statements."

d. Delete the "Personal Protective Equipment" section because this information has been incorporated into the "Precautionary Statements."

e. 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, 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 used on 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

SYMBOL	CONCURRENCE					
SURNAME	DATE					
DATE						

hemodialysis unit. There, the following language must be added below the "Disinfection" directions:

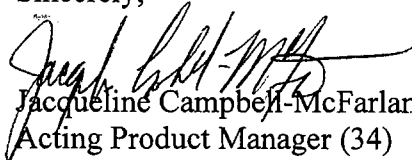
This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does 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.

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 by January 29, 2011, 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 or concerns regarding this letter, please contact Stacey Grigsby by telephone at (703) 308-6440 or by email at [grigsby.stacey@epa.gov](mailto:grigsby.stacey@epa.gov) or Jacqueline Campbell-McFarlane by telephone at (703) 308-6416 or by email at [Campbell-mcfarlane.jacqueline@epa.gov](mailto:Campbell-mcfarlane.jacqueline@epa.gov).

Sincerely,



Jacqueline Campbell-McFarlane  
Acting Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Enclosure: Stamped Label

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**IMPORTANT NOTICE**

This product is registered in both the U.S. and Canada  
It has BOTH U.S. and Canadian Labeling  
WHEN USING THIS product in the U.S. follow the U.S. information, where indicated  
WHEN USING THIS product in Canada, follow the Canadian information, where indicated

[FRONT PANEL]

**Denatured Alcohol 70%  
STER-AHOL Disinfectant  
WFI Formula**

**(Gamma Irradiated)**

**For Use in Clean Rooms and Controlled Areas**

**Hard Surface Disinfectant and Sanitizer**

**Active Ingredients:**

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

**Other Ingredients:**

USP Water for Injection.....30.0%

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

\*From Denatured Ethanol

\*\*This product contains >1% methyl alcohol

ACCOUNTED  
with 68959-R  
JAN 29 2010  
68959-1

**KEEP OUT OF REACH OF CHILDREN**

**WARNING - FLAMMABLE**

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

US EPA Reg. No.: 68959-R

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

Canadian DIN: xxxxxx

Net Contents: (In Canada XXXX mL or litres) ( In US XXX oz or gallons)

**Manufactured by:**

Veltek Associates, Inc.

15 Lee Blvd.

Malvern, PA 19355-1234

In Canada, distributed by:

Canada Clean Room (CCR) [www.ccrkanata.com](http://www.ccrkanata.com)

Ecolab [www.ecolab.com](http://www.ecolab.com)

VWR International [www.vwr.com](http://www.vwr.com)

Refer to product insert for further distributor contact information

Made in USA VAI {corporate logo}

<b>FIRST AID</b>	
<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 swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Move person to fresh air.</li> <li>• Do not induce vomiting unless told to by a poison control center or doctor.</li> <li>• Do not give anything to an unconscious person.</li> </ul>
<b>If inhaled</b>	<ul style="list-style-type: none"> <li>• Immediately remove the affected person to fresh air.</li> <li>• Call a poison control center or doctor for treatment advice</li> <li>• If not breathing, call ambulance, give artificial respiration, preferably mouth-to-mouth.</li> <li>• If breathing is difficult, give oxygen if qualified personnel are available.</li> </ul>
<b>If on skin</b>	<ul style="list-style-type: none"> <li>• Remove contaminated clothing, Wash with soap and water, rinse well</li> <li>• If irritation persists, Call a poison control center or doctor for treatment advice</li> <li>• Remove and wash clothing before re-use</li> </ul>

[BACK / SIDE PANELS]

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

~~WARNING: Not for personal use. Not for use on or around food. Do not get on skin or in eyes. Do not take internally and do not inhale vapor.~~

~~PHYSICAL AND CHEMICAL HAZARDS: This product may be irritating to the eyes, skin, gastrointestinal tract and respiratory system. May cause central nervous system depression.~~ Flammable liquid and vapor. Vapor may cause flash fire. Keep away from heat, sparks, direct sunlight, and open flame. Do not mix this product with other chemicals including: acids, oxidizing materials, combustible materials, halogens, peroxides, bases and metal salts.

~~PERSONAL PROTECTIVE EQUIPMENT: Wear eye protection goggles or face shield. Wear chemical-resistant gloves. Use supplied air respirators if levels exceed OSHA PEL.~~

#### DIRECTIONS FOR USE: Read the label and leaflet before using

In the United States: It is a violation of U.S. law to use this product without having obtained the U.S. label at the time of purchase and following the U.S. label at the time of application.

In Canada: This product is to be used only in accordance with the directions on the label. It is an offence to use this product in a way that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use of this product.

LOCATIONS OF USE: Disinfects and sanitizes cleanrooms and controlled areas such as those in health care institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. This product may be used to disinfect non-food contact, non-porous, inanimate, hard surfaces in areas such as: aseptic filling and gowning rooms, general manufacturing areas and laboratories. It may be used on surfaces, such as: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, plastic and glass. It is compatible with most hard surface materials.

DISINFECTION: Wear personal protection such as eye protection goggles or face shield. Wear chemical-resistant gloves. Use with adequate ventilation and spray away from eyes and face. If you experience eye watering, headaches or dizziness discontinue aerosolizing and inhaling fumes. STER-

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AHOL® is ready to use. Do not dilute. Pre-clean surface or item of heavy soil or gross filth before application. Hold container upright 6-12 inches (15-30 cm) from surface. Apply with saturated cloth or immerse item in a basin. Thoroughly wet surface with STER-AHOL® 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. Do not replace excess product into original container after use or after removal from original container, even if it was not used.

SANITIZATION: Follow all disinfection directions and allow to remain wet for a minimum of 5 minutes.

**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/Provincial/State regulations and Local/Municipal ordinances when disposing of this product. Improper disposal of excess product, spray mixture or rinse 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. 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.

**EMERGENCIES and FIRST RESPONDERS** – For Spill/Exposure Emergency Response Service in English or French (and 26 other languages) from USA or Canada 011-44-208-762-8322, Arabic +961 3 487 287, Chinese +86 10 5100 3039.

[back/side/bottom panel]

Lot number/ Batch Code: XXXXX

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

Optional Label Claims:

STER-AHOL 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 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.