

68959-1

08/30/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

AUG 30 2013

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Megan E. Pletka, Regulatory Consultant  
Veltek Associates, Inc.  
Technology Sciences Group Inc.  
1150 18<sup>th</sup> Street, NW, Suite 1000  
Washington, D.C. 20036

Subject: STER-AHOL® Disinfectant  
EPA Registration No.: 68959-1  
Notification Date: August 06, 2013  
EPA Receipt Date: August 06, 2013

Dear Ms. Pletka:

This letter acknowledges receipt of your notification submitted under the provisions of FIFRA and PR Notice 98-10.

**Proposed Notification**

- Adding alternate brand name: STER-AHOL®

**General Comments**

Based on a review of the submitted materials, to add the alternate brand name is **acceptable** and apart of the record on file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at [campbell.jacqueline@epa.gov](mailto:campbell.jacqueline@epa.gov) or Lorena Rivas by telephone at (703) 305-5027 or by e-mail at [rivas.lorena@epa.gov](mailto:rivas.lorena@epa.gov). When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacqueline Campbell".

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

	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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**Application for Pesticide – Section I**

1. Company/Product Number <b>68959-1</b>	2. EPA Product Manager <b>Jacqueline Campbell</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>STER-AHOL® Disinfectant</b>	PM# <b>34</b>	
5. Name And Address Of Applicant (Include ZIP Code) <b>Veltek Associates, Inc.</b> <b>15 Lee Boulevard</b> <b>Malvern, PA 19355-1234</b>  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section II**

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain Below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

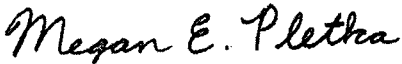
**Notification to add Alternate Brand Name per PR Notice 98-10.**

**This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.**

**Section III**

1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted If "Yes"                      No. per Unit Packaging wgt.      Container		If "Yes"                      No. per Unit Packaging wgt.      Container	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Other _____ <input type="checkbox"/> Pager glued <input type="checkbox"/> Stenciled			

**Section IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name <b>Megan E. Pletka, Technology Sciences Group, Inc.</b>	Title <b>Regulatory Consultant</b>	Telephone No. (Include Area Code) <b>(202) 828-8954</b>
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received _____ (Stamped)
2. Signature 	3. Title <b>Regulatory Consultant to Veltek Associates, Inc.</b>	
4. Typed Name <b>Megan E. Pletka</b>	5. Date <b>August 6, 2013</b>	



**Technology Sciences Group Inc.**

1150 18<sup>th</sup> Street, Suite 1000  
Washington, DC 20036  
Direct: (202) 828-8954  
Fax: (202) 872-0745  
E-Mail: mpletka@TSGUSA.com

**Megan E. Pletka**  
Regulatory Consultant

August 6, 2013

**Veltek Associates, Inc.**  
**Notification to Add Alternate Brand Name**  
**NAFTA Label for STER-AHOL® Disinfectant**  
**EPA Reg. No. 68959-1**

Ms. Jacqueline Campbell (PM-34)  
Antimicrobials Division (7510P)  
Office of Pesticide Programs (NOTIF)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202

Dear Jacqueline:

Technology Sciences Group, Inc., on behalf of Veltek Associates, Inc. (Veltek), is submitting the enclosed label notification to add an alternate brand name for STER-AHOL® Disinfectant. Specifically, the alternate brand name "STER-AHOL®" is being added to this product to account for an error in EPA's NPIRS database. Specifically, EPA's NPIRS database lists the name for this product as "STER-AHOL®" rather than the correct name of "STER-AHOL® Disinfectant" as seen on the product label and in EPA correspondence. The optional marketing claims on the label are also being updated to reflect the new alternate brand name.

Supporting this label notification, please find enclosed the following documents:

- 1) EPA Application Form (EPA Form 8570-1);
- 2) Proposed NAFTA label with changes indicated;
- 3) Proposed NAFTA label – clean copy.

If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8954 or by e-mail at [mpletka@tsgusa.com](mailto:mpletka@tsgusa.com).

Sincerely,

*Megan E. Pletka*

Regulatory Consultant to  
Veltek Associates, Inc.

Enclosures

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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

**STER-AHOL® Disinfectant**  
**{Alternate Brand Name: STER-AHOL®}**

**\*\*WFI Formula**

**(Gamma Irradiated)**

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

**Hard Surface Disinfectant**

**Active Ingredients:**

\*Ethanol mixture .....70.0%

**Other Ingredients:**

\*\*Water.....30.0%

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

\*Ethyl alcohol denatured with methyl alcohol and isopropyl alcohol; contains less than 3.5% methyl alcohol

\*\*USP Water for Injection



**KEEP OUT OF REACH OF CHILDREN**

**WARNING - FLAMMABLE**

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

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

See container for lot number and storage expiration date.

**US EPA Reg. No.:** 68959-1

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

**Canadian DIN:** 02351250

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

200 Terrence Matthews

Kanata ON K2M 2C6

Veltek Associates – STER-AHOL DISINFECTANT (EPA Reg. No. 68959-1)

NAFTA - Label version (9) dated October 19, 2012 August 6, 2013

### 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 five 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:** Immediately remove the affected person to fresh air. Call a poison control center or doctor for treatment advice. If not breathing, call 911 or ambulance, give artificial respiration, preferably mouth-to-mouth. If breathing is difficult, give oxygen if qualified personnel are available.

**If swallowed:** 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.

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

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**WARNING:** Causes substantial but temporary eye injury. Harmful if absorbed through the skin. Avoid contact with eyes, skin, or clothing. Avoid breathing spray mist. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**PHYSICAL AND CHEMICAL HAZARDS:** 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.

### DIRECTIONS FOR USE

**Read the label before using**

In the United States: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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.

**USE:** Disinfects and sanitizes cleanrooms and controlled areas such as those in health care institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. Use on non-food contact, hard non-porous, inanimate surfaces in areas such as: 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 hard non-porous materials such as glass, plastic, vinyl, chrome, and stainless steel. It is compatible with most hard surface materials.

**DISINFECTION:** 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® is ready to use. Do not dilute. Pre-clean all surfaces prior to disinfecting. Hold container upright 6-8 inches (15-20 cm) from surface or 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.

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 normal sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high level disinfection.

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:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. If 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:** 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.

**User Information**

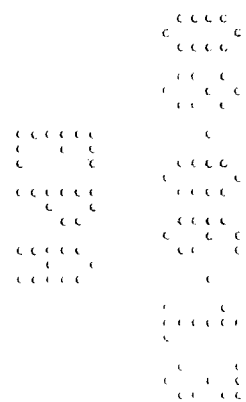
Date Opened/Operator:

Expiration Date:

Area:

Lot number/ Batch Code: XXXXX

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



Optional Label Claims:

| (STER-AHOL®)(STER-AHOL® Disinfectant) (This product) 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®)(STER-AHOL® Disinfectant) (This product) 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.

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

| (STER-AHOL®)(STER-AHOL® Disinfectant) —STER-AHOL®(This product) is sterilized for aseptic use.

| (STER-AHOL®)(STER-AHOL® Disinfectant) STER-AHOL® Aerosol(This product) is sterilized by gamma irradiation.

