

68959-1

11-23-2011

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

NOV 23 2011

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Heather Bjornson  
Veltek Associates, Inc.  
15 Lee Blvd  
Malvern, PA 19355

Subject: STER-AHOL Disinfectant  
EPA Registration No.: 68959-1  
Amendment Date: August 29, 2011  
EPA Receipt Date: August 29, 2011

Dear Ms. Bjornson:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with conditions.

**Proposed Amendment**

- Correct active ingredient statement and remove NAFTA labeling

**Conditions**

Revise the label as follows:

- 1.) Revise the 6<sup>th</sup> statement in the "Precautionary Statements" section on page 2 by adding the phrase, "or using the toilet," at the end of the sentence.

**General Comments**

A stamped label with conditions is enclosed for your records. Submit a final printed label before distributing or selling this product bearing the revised labeling.

If you have further questions concerning this letter, please contact me Glen McLeod by telephone at (703) 347-0181 or by email at [mcleod.glen@epa.gov](mailto:mcleod.glen@epa.gov).

Sincerely,

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



United States  
**Environmental Protection Agency**  
 Washington, DC 20460

<input type="checkbox"/>	Registration
<input checked="" type="checkbox"/>	Amendment
<input type="checkbox"/>	Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 68959-1	2. EPA Product Manager Jacqueline Campbell McFarlane	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) STER-AHOL Disinfectant	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Veltek Associates Inc. 15 Lee Blvd. Malvern, PA 19355 <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 type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

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

This fast-track amendment is to update the active ingredient statement and also remove all NAFTA language to make this solely a US label as well as other minor text revisions.

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
				<input checked="" type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 11,16, 22 oz bot/cans and 32 oz.bags		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled			<input type="checkbox"/> Other _____		

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather R. Bjornson	Title Senior Regulatory Consultant	Telephone No. (Include Area Code) (202) 628-8945
<b>Certification</b> 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  <b>(Stamped)</b>
2. Signature 	3. Title Regulatory Consultant to Veltek Associates Inc.	
4. Typed Name Heather R. Bjornson	5. Date August 29, 2011	



**Technology Sciences Group Inc.**

1150 18<sup>th</sup> Street, NW, Suite 1000  
Washington, D.C. 20036  
Direct: (202) 828-8945  
Fax: (202) 872-0745  
E-Mail: hbjornson@tsgusa.com

**Heather R. Bjornson**  
Senior Regulatory Consultant

Jacqueline Campbell - McFarlane, PM 34  
Office of Pesticide Products, US EPA  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

August 29, 2011

RE: STER-AHOL<sup>®</sup> Disinfectant (EPA Reg. No. 68959-1)

Fast-track label amendment

Dear Ms. Campbell - McFarlane:

Technology Sciences Group Inc., on behalf of Veltek Associates Inc., is submitting the enclosed fast-track label amendment to: 1) correct the active ingredient statement; 2) make this solely a US label (eliminate the Canadian portion), 3) add additional claims, and 4) make minor text revisions.

You will find the following included to support this amendment:

- 1. Application form;
- 2. One redline version of the label, and
- 3. Three clean copies of the revised label.

Should you have any questions or comments, please do not hesitate to contact me directly.

Sincerely,

Heather R. Bjornson



714

**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 Denatured Ethanol .....70.0%

**Other Ingredients:**

USP Water for Injection.....30.0%

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

\*This product contains >1% methyl alcohol

**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

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

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

**Net Contents:** (XXX oz or gallons)

**Manufactured by:**

Veltek Associates, Inc.

15 Lee Blvd.

Malvern, PA 19355-1234

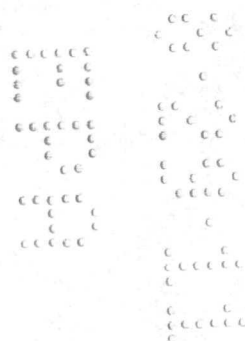
Made in USA VAI {corporate logo}

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

NOV 23 2011

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

68959-1





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### 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 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 and clothing</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>
<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>

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**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.

**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 and leaflet before using

It is a violation of U.S. law to use this product without having obtained the U.S. label

**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-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 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 mucus 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 of 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.

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

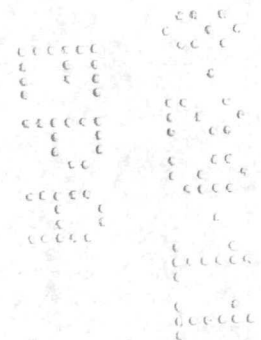
**Pesticide Disposal:** Wastes resulting from the use of this product must be disposed of in site or at an approved waste disposal facility.

**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.

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

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.

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

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

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

