

68959-3

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 16, 2012

Micah T. Reynolds
Regulatory Consultant for Veltek Associates, Inc.
Technology Sciences Group Inc.
1150 18th Street, NW, Suite 1000
Washington, D.C. 20036

Subject: STER-AHOL[®] Aerosol
EPA Registration No.: 68959-3
Application Date: 07/18/2012
Receipt Date: 07/18/2012

Dear Mr. Reynolds:

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with conditions.

Proposed Amendment

- NAFTA label

Conditions

Please revise the label as follows:

1. Please add the asterisk to clarify what WFI stands for.
2. Please add a note to the reviewer to explain that the optional text are affixed to the type of spray nozzle of that product container. The Agency accepts the representative dots.
3. Delete "splashed" in the First Aid heading "If splashed in eyes" to read "If in eyes."
4. Reorganize the first aid statements to appear in the following order per the toxicity:
"If in eyes,..."
"If on skin or clothing,..."
"If inhaled,..."

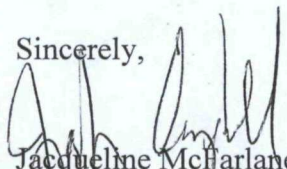
5. Add the following statement to appear in the Precautionary statements:
"Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."

6. Keep the term "explosive" or remove and add graphic of fire to indicate high flammability.

General Comments

A stamped label is enclosed for your records. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

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-mcfarlane.jacqueline@epa.gov or Jaclyn Carl by telephone at (571) 384-5684 or by e-mail at carl.jaclyn@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,

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

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

[Alternate Brand Name: STER-AHOL® INVERTASPRAY]

STER-AHOL® Aerosol

WFI Formula

[●Mist {or} ●stream]
Dot indicates spray pattern.

[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

{symbol for pressurized can}



KEEP OUT OF REACH OF CHILDREN

WARNING – 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

ACCEPTED
with COMMENTS
EPA Letter Dated:

OCT 16 2012

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the year 2012,
registered under EPA Reg. No.

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US EPA Reg. No.: 68959-3
US EPA Est. No.: 68959-PA-001
Canadian DIN: 02351226

Manufactured by:
Veltek Associates, Inc.
15 Lee Blvd.
Malvern, PA 19355-1234
Inquiries: (888) 595-8070

In Canada: Distributed by:
Canada Clean Room
280 Terence Mathews
Kanata ON K2M 2C6

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

Made in USA VAI {corporate logo}

FIRST AID

If splashed 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 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 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.

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 skin. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Wear protective eyewear.

PHYSICAL AND CHEMICAL HAZARDS: 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.

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 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® Aerosol is ready to use. Pre-clean all surfaces prior to disinfecting. Hold can upright 6-8 inches (15-20 cm) 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.

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).

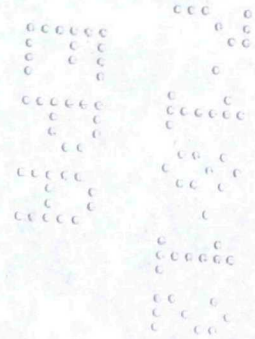
Disposal: Wastes resulting from the use of this product must be disposed of in site or at an approved waste disposal facility. If wastes cannot be disposed of by use according to label instructions, contact your Federal/Provincial/State or Local/Municipal environmental control agency for guidance.

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.

{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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User Information
Date Opened/Operator: <input type="text"/>
Expiration Date: <input type="text"/>
Area: <input type="text"/>

Optional Label Claims:

STER-AHOL® Aerosol is bactericidal. The results of AOAC Efficacy Tests show that STER-AHOL Aerosol is an effective hard surface disinfectant against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC#6538), and *Salmonella enterica* (ATCC#10708) 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 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.

