

68959-3

05/14/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

May 14, 2012

Micah T. Reynolds, Agent for Veltek Associates
c/o Technology Sciences Group, Inc.
1150 18th Street, Suite 1000
Washington D.C. 20036

Subject: Ster-Ahol
EPA Registration Number: 68959-3
Application Date: April 9, 2012

Dear Mr. Reynolds:

The Agency has reviewed your submission in accordance with continuing registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended, and determined the action to be acceptable with the following comment.

- The addition to our files of your alternate brand name, Ster-Ahol Invertespray, is formally approved.

In summary, your request to revise the description of the ingredient statement has been reviewed and the label changed accordingly.

A copy of your stamped accepted label is enclosed. You must provide a copy of your finished labeling for our files. If you have any questions about this letter, please contact Tom Luminello by telephone, (703) 308-8075, or by e-mail at luminello.tom@epa.gov.

Sincerely,

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

[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:

*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

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.: 68959-3
EPA Est. No.: 68959-PA-001

Manufactured by:
Veltek Associates, Inc.
15 Lee Blvd.
Malvern, PA 19355-1234

ACCEPTED
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Net Contents: (XXX oz or gallons)

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FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.
<p>Have the product container or label with you when calling a poison control center or doctor or going to treatment. For emergency information, call the National Pesticide Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center at 1-800-222-1222.</p>	

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PRECAUTIONARY STATEMENTS

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. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothes. Wear long sleeves and long pants, socks and shoes, and chemical resistant gloves.

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

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.

TO DISINFECT: 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 all surfaces prior to disinfecting. 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.

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 or high level disinfection.

TO SANITIZE: Use this product wearing personal protection such as goggles and gloves. Use adequate ventilation and spray away from eyes and face. Pre-clean all surfaces prior to sanitizing.

Hold can upright 6-12 inches from surface. Thoroughly wet surfaces for a minimum of 5 minutes. Allow surface to dry, or after 5 minutes wipe dry with sterilized cloth, wiper, if needed.

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.

{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 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.

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