

68959-1

5/14/2012

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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

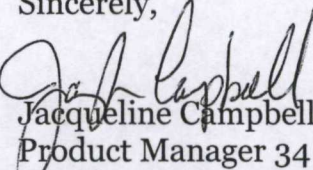
Subject: Ster-Ahol
EPA Registration Number: 68959-1
Application Date: April 9, 2012

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.

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,

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

STER-AHOL® Disinfectant
WFI Formula

(Gamma Irradiated)

For Use in Clean Rooms and Controlled Areas

Hard Surface Disinfectant and Sanitizer

Active Ingredients:

*Ethanol mixture70.0%

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

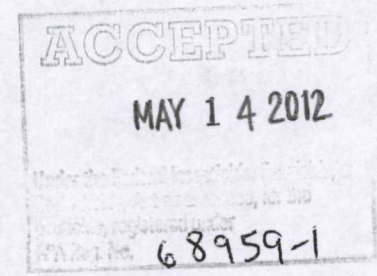
WARNING - FLAMMABLE

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



FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Immediately remove the affected person to fresh air. • Call a poison control center or doctor for treatment advice • If not breathing, call ambulance, give artificial respiration, preferably mouth-to-mouth. • If breathing is difficult, give oxygen if qualified personnel are available.
If on skin and clothing	<ul style="list-style-type: none"> • Remove contaminated clothing, Wash with soap and water, rinse well • If irritation persists, Call a poison control center or doctor for treatment advice • Remove and wash clothing before re-use
If swallowed	<ul style="list-style-type: none"> • 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.

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

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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.

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).

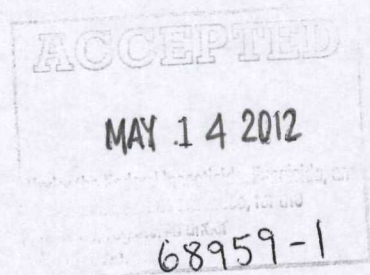
Pesticide Disposal: Wastes resulting from the use of this product must be disposed of in site or at an approved waste disposal facility.

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.

