

68959-1

10/9/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

October 9, 2012

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

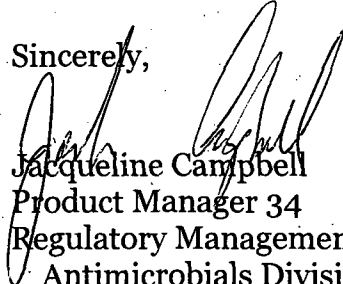
Subject: Ster-Ahol, NAFTA label
EPA Registration Number: 68959-1
Application Date: April 9, 2012

Dear Mr. Reynolds:

The referred to above, submitted in connection with registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended, to review the product labeling under the NAFTA labeling process, is acceptable.

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)

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
WFI Formula

(Gamma Irradiated)

For Use in Clean Rooms and Controlled Areas

Hard Surface Disinfectant

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

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
Inquiries: (888) 595-8070

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

Made in USA VAI {corporate logo}

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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registered under EPA Reg. No. 68959-1

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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: 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 contaminated clothing before re-use.

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 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.

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, 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, vinyl, chrome, stainless steel 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. 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 6-8 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.

ACCEPTED

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

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

NAFTA - Label version (8) dated July 16, 2012

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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.

User Information

Date Opened/Operator:

Expiration Date:

Area:

Lot number/ Batch Code: XXXXX

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

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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.

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