



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 22, 2016

Heather Bjornson-Lam
Senior Regulatory Consultant
Veltek Associates, Inc.
15 Lee Blvd.
Malvern, PA 19355

Subject: Label Amendment – Add the word “sterile” to product description
Product Name: Ster-ahol Aerosol
EPA Registration Number: 68959-3
Application Date: March 22, 2016
Decision Number: 515578

Dear Ms. Bjornson-Lam:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

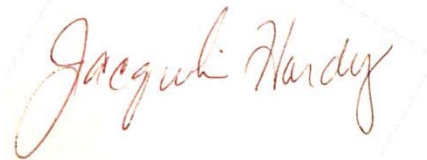
Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Tom Luminello by phone at 703-308-8075, or via email at luminello.tom@epa.gov.

Sincerely,

A handwritten signature in red ink that reads "Jacqueline Hardy". The signature is written in a cursive style and is enclosed within a faint, light-colored rectangular border.

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

Enclosure – Stamped Label

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® WFI Formula INVERTASPRAY, STER-AHOL® AEROSOL WFI Formula INVERTASPRAY]

STER-AHOL® Aerosol

****WFI Formula**

[●Mist {or} Stream●]

[Red] Dot indicates spray pattern.

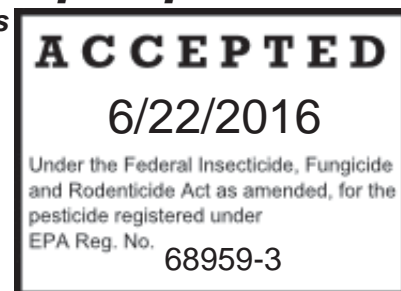
(Note to Reviewer: The above illustrated "dots" indicate to the customer what type of spray nozzle type is affixed to the container – a mist nozzle or a spray nozzle. Dots are placed as examples of placement adjacent to spray nozzle type.)

[Gamma Irradiated]

[The Inverta-Spray System]

[Sterile]

**For Use in Clean Rooms and Controlled Areas
Hard Surface Disinfectant**



Active Ingredient:

*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**

Keep away from heat or open flame.

Contents under pressure

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

(Note to reviewer: The following reference statements available for various packaging scenarios.)

See [side] [other] [back] [case label] [panel] [and/or] [package insert] for [first aid] [precautionary statements] [directions for use] [additional precautions] [and] additional product information].

[Refer to the primary case label for [additional] precautionary statements, directions for use, and additional product information]

[Peel [here] [back] for [Spanish and] additional information]

[See container for lot number and storage expiration date]

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) 478-3745

In Canada: Distributed by:

Canada Clean Room

200 Terrence Matthews

Kanata ON K2M 2C6

Inquiries: (888) 595-8070

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

Made in USA VAI {corporate logo}

FIRST AID

If 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 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.

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.

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. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

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 on 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 or incinerate. 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

[MSDS] [No.]: XXXXX

[Label No. XXXXX]

[Reorder #]: XXXXX

[Rev XX/XX]

[US Patent 6,123,900, 6,333,006, 6,607,695]

User Information

Date Opened/Operator:

Expiration Date:

Area:

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.