



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 21, 2016

Heather Bjornson-Lam
Regulatory Consultant
Veltek Associates, Inc.
15 Lee Boulevard
Malvern, PA 19335

Subject: Label Amendment – Adding Sterile Claim
Product Name: DECON-AHOL Aerosol
EPA Registration Number: 68959-4
Application Date: March 22, 2016
Decision Number: 515726

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 Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao".

Julie Chao, Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Approved 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: DECON-AHOL® WFI Formula INVERTASPRAY, DECON-AHOL® AEROSOL WFI Formula INVERTASPRAY]

DECON-AHOL®^{mc} 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:

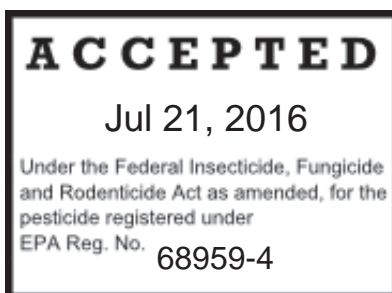
Isopropyl Alcohol CAS# 67-63-0.....70.0%

Other Ingredients:

*Water.....30.0%

Total:.....100.0%

*USP Water for Injection



KEEP OUT OF REACH OF CHILDREN

DANGER
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.: 68959-4

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

Canadian DIN: 02351382

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)

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]

[Made in USA]

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 poison control center or doctor for treatment advice.
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.• Have product container or label with you when calling a poison control center or doctor, or going for treatment.
If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call 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 poison control center or doctor for treatment advice.
EMERGENCIES: 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

DANGER: Corrosive. Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes or on clothing. Avoid breathing vapor or spray mist. Avoid contact with skin or clothing. Wear protective eyewear such as goggles or face shield, protective clothing and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PHYSICAL AND CHEMICAL HAZARDS: Contents under pressure. Flammable liquid and vapor.

Vapor may cause flash fire. Keep away from heat, sparks, and open flame. Do not mix this product with other chemicals including: acids, oxidizing materials, combustible materials, halogens, peroxides, bases and metal salts. 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.

*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 normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.*

USE: Disinfects and sanitizes cleanrooms and controlled areas including those used in healthcare institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. Use on hard, non-porous, inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas, 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. Wear protective eyewear such as goggles or face shield, protective clothing and chemical-resistant gloves. Use with adequate ventilation and spray away from eyes and face. DECON-AHOL AEROSOL is ready to use. Pre-clean surface or item of heavy soil or gross filth before application. Hold can upright 6-12 inches from surface. Thoroughly wet surface with DECON-AHOL AEROSOL and allow to remain wet for 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth, wiper, if needed.

DECON-AHOL AEROSOL is bactericidal. The results of AOAC Efficacy Tests show that DECON-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.

SANITIZATION: Use a 5 minute contact time on hard, non-porous 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.

DECON-AHOL AEROSOL is an effective sanitizer on hard, non-porous, inanimate, non-food contact surfaces against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella pneumoniae* (ATCC#4352) in 5 minutes.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in the original container in a dry cool place below 48.8°C (120° F).

Disposal: Product and product wastes are toxic. Follow Federal/Provincial/State regulations and Local/Municipal ordinances when disposing of this product. Improper disposal of excess product is a violation of Federal/Provincial/State Laws. If these 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 Disposal:** Non-refillable pressurized container. Do not re-use or refill this container. Do not puncture or incinerate. If empty, offer for recycling, if available. If partly filled: call local solid waste agency for disposal instructions.

User Information

Date Opened/Operator:

Expiration Date:

Area: