



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

February 5, 2025

Heather Bjornson-Lam
Veltek Associates, Inc.
Electronic Transmittal: heather.bjornson@sterile.com

Subject: PRIA Label and CSF Amendment – To reduce contact times for public health microorganisms and modify the active ingredient statement.
Product Name: DECON-AHOL
EPA Registration Number: 68959-2
Received Date: 9/28/2023
Action Case Number: 00491721

Dear Heather Bjornson-Lam:

The amended label and CSF(s) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are 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. Pursuant to 40 CFR 156.10(a)(6), 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.

Please note that the record for this product currently contains the following CSF(s):

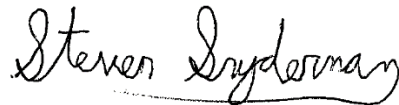
- Basic CSF dated 7/2/2024

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 FIFRA and is subject to review by the

Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

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 with FIFRA section 6. If you have any questions, please contact Srinivas Gowda by phone at 202-565-0078 or via email at gowda.srinivas@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive style with a horizontal line underneath the name.

Steven Snyderman, Product Manager 33
Regulatory Management Branch II
Antimicrobials Division (7510M)
Office of Pesticide Programs

Enclosures:

AD Product Chemistry Review_DECON-AHOL_EPA Reg. No. 68959-2_Action Code: 00491721.
AD Efficacy Science Review_DECON-AHOL_EPA Reg. No. 68959-2_Action Code: 00491721

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

DECON-AHOL

WFI Formula

[Gamma Irradiated] [*Sterile][Pharmaceutical Cleanroom Formula][Formulated with USP Water for Injection (WFI) Quality Water][Filtered at 0.2 µm]

**For Use in Clean Rooms and Controlled Areas
Hard Non-porous Surface Disinfectant and Sanitizer**

Active Ingredients:

Isopropyl Alcohol CAS# 67-63-065.4% (equivalent to 70% v/v)

Other Ingredients:

USP Water for Injection..... 34.6%

Total:..... 100.0%

*Per USP <71>

KEEP OUT OF REACH OF CHILDREN



{Optional GHS symbols}

DANGER – FLAMMABLE

[Note to Reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label.]

Keep away from heat or open flame.

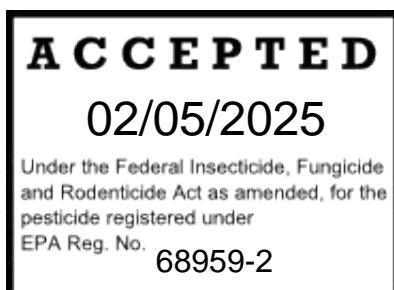
Store at room temperature below 48.8°C (120°F){Note to reviewer: The following reference statements available for various packaging scenarios.}

[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]



{Lot Label Sticker}	
Reorder [xxxxxxxxxxxxx]	[QR Code]
Lot: [xxxxxxx]	
EXP. [dd-MM-YYYY]	
Net Contents: [(XXX mL /L) on Container or on Case (XX/CASE, Container size (yyy))]	

[See container for red irradiation indicator {will not appear on non-sterile packages}] • Rev. M#/YY • [SDS document code]

US EPA Reg. No.: 68959-2
US EPA Est. No.: For EPA Est. No. see the final character of the lot #: L = 68959 –PA-01, C = 68959-PA-03, T = 68959-PA-02

Canadian DIN: 02351374

Manufactured by:
 Veltek Associates, Inc.
 15 Lee Blvd.
 Malvern, PA 19355-1234
 Tel: 1-610-644-8335
 www.sterile.com
 Patents: www.sterile.com/patents

In Canada Distributed by:
 XXXXXXXXXXXXXXXX
 XXXXXXXXXXXXXXXX
 XXXXXXXXXXXXXXXX
 Inquiries: (XXX) XXX-XXXX

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

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 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. • Call a poison control center or doctor for treatment advice.
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 a poison control center or doctor for treatment advice.
EMERGENCIES: In the case of emergency call: 1-866-928-0789 (toll free, USA), 1-800-579-7421 (toll free, Canada), 1-215-207-0061 (Americas), or +52 55 5004 8763 (México)	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: 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 chemically resistant gloves. Wash thoroughly with soap and water after handling, 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.

This product may be irritating to the eyes, skin, gastrointestinal tract and respiratory system. May cause nervous system depression.

PHYSICAL AND CHEMICAL HAZARDS: Flammable liquid and vapor. Vapor may cause flash fire. Keep away from heat or open flame. Exposure to temperature above 48.8°C (120° F) may cause bursting. 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

In the United States: It is a violation of U.S. 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 hard, non-porous surfaces in cleanrooms and controlled areas such as those used in healthcare institutions, biopharmaceutical, pharmaceutical, diagnostic and medical device manufacturing facilities. Use on hard non-porous inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas, or on machinery, tables, counters, laminar flow benches, floors, walls, carts, shelves made of hard non-porous materials such as glass, Corian™, laminate flooring, aluminum, pvc, mild steel, polypropylene, plastic, vinyl, chrome, and stainless steel. It is compatible with most hard surface materials.

DISINFECTION: DECON-AHOL is ready to use. Do not dilute. Pre-clean surface or item before application. For Spray applications, hold bottle upright 6-8 inches or 15-30 cm from surface. Thoroughly wet surface with DECON-AHOL and allow to remain wet for a minimum of 2 minutes. Allow surface to air dry, or after 2 minutes wipe dry with sterilized cloth, wiper, if needed.

DECON-AHOL is bactericidal. The results of AOAC Efficacy Tests show that DECON-AHOL is an effective hard surface disinfectant against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC#6538), and *Salmonella enterica* (ATCC#10708) in 2 minutes.

SANITIZATION: Pre-clean surface or item before application. Thoroughly wet surface with DECON-AHOL and allow to remain wet for a minimum of 30 seconds. Allow surface to air dry, or after 30 seconds wipe dry with sterilized cloth, wiper, if needed.

DECON-AHOL is an effective sanitizer on inanimate, non-food contact surfaces against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella aerogenes* (ATCC# 13048) in the presence of fetal bovine serum organic load in 30 seconds.

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). Absorb spills with inert material (e.g. dry sand or earth dry), then place in a chemical waste container.

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, spray mixture or rinsate 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. Contaminated absorbent in drums must be disposed of via an authorized waste disposal contractor. Never place unused product down any indoor or outdoor drain.

Container Disposal: Non-refillable container. Do not reuse or refill this container to hold materials other than pesticides and diluted pesticides (rinsate). Dispose of container by permitted onsite incinerator or by transport to offsite permitted incineration service. If incineration is unavailable triple rinse container promptly after emptying. Triple rinse as follows [(for containers less than 5 gallons) Fill container ¼ full with water and recap. Shake 10 seconds. Follow Pesticide disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat two more times.] [(for containers greater than 5 gallons) Fill container ¼ full with water. Tip the container on its side and roll it back and forth, ensuring one complete revolution for 30 seconds. Stand container on its end and tip it back and forth several times. Follow pesticide disposal instructions for rinsate disposal. Drain for 10 seconds after flow begins to drip. Repeat two more times.] Offer for recycling where available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

{Note: To appear as label end panel for customer use on containers: convenience item.}

User Information
Date Opened/Operator:
<input type="text"/>
Expiration Date:
<input type="text"/>
Area:
<input type="text"/>

Lot number/ Batch Code: XXXXX

EXPIRY: day/MONTH/year. Once opened use within (60 Days)

[SDS] [No.] XXXXX

[Label No. XXXXX]

[Reorder # XXXXX]

[Rev XX/XX]

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

Optional Claims:

SANITIZATION: Use 30 seconds 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® has been developed for use in cleaning rotation cycles where hard surface disinfectants are essential for reducing cross-contamination.
- DECON-AHOL® has been formulated as a sterile pharmaceutical cleanroom formula.
- *Sterile pharmaceutical cleanroom formula.
- Made in the USA