

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Antimicrobials Division (7510P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460

68959-14

Date of Issuance:

EPA Reg. Number:

9/16/2024

NOTICE	OF	PES7	ΓICII	E:
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X Registration Reregistration (under FIFRA, as amended)

Unconditional

Term of Issuance:

Name of Pesticide Product:

DECON-AHOL® WIPE

Name and Address of Registrant (include ZIP Code):

Veltek Associates, Inc. 15 Lee Boulevard Malvern, PA 19355

Electronic Transmittal: Heather.Bjornson@sterile.com

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

- 1. Submit and/or cite all data required for registration/registration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
- 2. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 68959-14."

Signature of Approving Official:	Date:
March Ctopfail	
Marcel Howard, Product Manager 34 Regulatory Management Branch 2 Antimicrobials Division (7510M)	9/16/2024

EPA Form 8570-6

Page 2 of 2

EPA Reg. No. 68959-14

Action Code Case: 00343571

3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

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.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

Basic CSF dated 10/11/2023

If you have any questions, please contact Lorena Rivas, via email at rivas.lorena@epa.gov.

Enclose: Stamped Label

DECON-AHOL® WIPE WFI Formula

For Use in Cleanrooms and Controlled Areas

Hard Surface Disinfectant and Sanitizer
[Formulated with USP Water for Injection Quality Water (0.25 EU/mL)]

(Aseptically Filtered at 0.2 µm) (Sterile)

ACCEPTED

09/16/2024

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 68959-14

KEEP OUT OF REACH OF CHILDREN DANGER

{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: {xxxxxxxxx}

EXP. {dd-MM-YYYY}

Net Contents: {XXX (Individually Packaged) Wipes, Size, Weight}

EPA Reg. No.: 68959-14

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

Patents: www.sterile.com/patents

Manufactured by:

Veltek Associates, Inc. 15 Lee Blvd. Malvern, PA 19355-1234

Red dot indicates Sterile {will not appear on non-sterile packages} Rev. MM#/YY ●{code}

(Made in Korea to VAI Quality Standards) 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	Take off contaminated clothing.	
clothing	 Rinse skin immediately with plenty of water for 15 – 20 minutes. 	
	Call a poison control center or doctor for treatment advice.	
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.	
If inhaled	Move person to fresh air.	
	If person is not breathing, call 911 or an ambulance, them give artificial	
	respiration, preferably mouth-to-mouth if possible.	
	Call poison control center or doctor for treatment advice.	
Note to Physician	n: Probable mucosal damage may contraindicate the use of gastric lavage.	

EMERGENCIES: Have the product container with you when calling a poison control center or doctor or going for treatment. In the case of emergency call: 1-866-928-0789 (toll free) or 1-215-207-0061 (Americas), +52 55 5004 8763 (México)

[BACK / SIDE PANELS]

Si usted no etiende la etiqueta, busque a alguien para que se la explique a usted En detalle.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive, Causes irreversible eye damage. Maybe harmful if swallowed, absorbed by the skin or inhaled. Avoid contact with eyes, skin or clothing or breathing vapor. Do not get in eyes, on skin, or on 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 clothing 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 central nervous system depression.

PHYSICAL AND CHEMICAL HAZARDS: Flammable. 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. Exposure to temperatures above 48.8°C (120° F) may cause bursting.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is <u>NOT</u> 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.

LOCATIONS OF USE: Cleanrooms and controlled areas such as those in health care 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 and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, Corian™, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel. It is compatible with most non-porous hard surface materials.

Multi Pack

Open Package. Pull out wipes as needed and reseal. When not in use keep sealed to prevent moisture loss. (Peel (and) (or) Reseal Here).

Individual Wrapped Pack

Tear open packet. Unfold.

DISINFECTION: DECON-AHOL WIPE are an effective hard non-porous surface disinfectant against *Pseudomonas aeruginosa (ATCC# 15442), Staphylococcus aureus (ATCC#6538) in* 1 minute.

Pre-clean all surfaces or pre-clean with DECON-AHOL WIPE and dispose. Using fresh DECON-AHOL WIPE thoroughly wet surface to disinfect. Surface must remain visibly wet for a minimum of (one) (1) minute. Allow surface to air dry, or after 1 minute, wipe dry if needed.

SANITIZATION: DECON-AHOL WIPE are an effective sanitizer on inanimate, hard non-porous, non-food contact surfaces against *Staphylococcus aureus* (ATCC#6538) and Klebsiella pneumoniae (ATCC#4352) in 30 seconds.

Pre-clean all surfaces or pre-clean with DECON-AHOL WIPE and dispose. Using fresh DECON-AHOL WIPE thoroughly wet surface to sanitize. Surface must remain visibly wet for a minimum of 30 seconds.. Allow surface to air dry, or after 30 seconds, wipe dry if needed.

Storage and Disposal

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

Pesticide Storage: Store in original container in a cool, well-ventilated area. Do not store near heat or open flame.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate from container is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your state Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling:

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

Wipes Disposal:

Nonreusable one-time use container. Discard used and unused wipes in trash. Do not flush wipes down toilet.

Optional Label Claims:

Disinfectant (in 1 Minute)
Hard Surface Disinfectant
Sanitizer (in 30 Seconds)
Non-Food Contact Sanitizer
(Saves Time) Fast Sanitizing Contact Time (30 seconds)
Leaves No Residue
Ready to Use
Bleach Free
Ideal for cleaning and disinfecting hard, non-porous surfaces
May be used daily
One Minute (Disinfectant Formula) (Kill Time) (Contact Time)
For use in Cleanroom Environments

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

Processed, Filled, Packaged, Sterilized and Tested in the USA. Dry wipes made in South Korea.

User	Information		
Date Opened/Operator:			
Expire	lion Date:		
Arez:			

