

68959-4

12/10/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

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

DEC 10 2013

Attention: Micah T. Reynolds

**Subject:** DECON-AHOL Aersol  
EPA Registration No: 68959-4  
Notification Dated: October 8, 2013

This will acknowledge receipt of your notification submitted under PR Notice 98-10 and make other minor changes to the product label, submitted under the provision of FIFRA Section 3(c)(9).

**Proposed Notification:**

To add additional brand names

**General Comments:**


Based on a review of the submitted material, the following comments apply:

The Notification dated October 8, 2013 to add the new alternate brand names "DECON-AHOL® WFI Formula INVERTASPRAY", "DECON-AHOL® AEROSOL WFI Formula INVERTASPRAY" is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Zebora Johnson at (703) 308-63417.

Sincerely

Marshall Swindell  
Product Manger (33)  
Regulatory Management Branch I  
Antimicrobial's Division (7501P)

	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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**Application for Pesticide – Section I**

1. Company/Product Number <b>68959-4</b>	2. EPA Product Manager <b>Marshall Swindell</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>DECON-AHOL Aerosol</b>	PM# <b>33</b>	
5. Name And Address Of Applicant (Include ZIP Code) <b>Veltek Associates, Inc. 15 Lee Boulevard Malvern, PA 19355-1234</b>		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____
<input type="checkbox"/> Check if this is a new address		

**Section II**

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain Below.

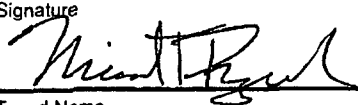
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

**Submission of Label Notification to add alternate brand names, packaging specific text, and other non-FIFRA language.**  
 This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Please confirm receipt with Micah Reynolds: [mreynolds@tsgusa.com](mailto:mreynolds@tsgusa.com), via phone (202) 828-8967, or via fax (202) 872-0745.

**Section III**

1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt.    No. per Container	If "Yes" Unit Packaging wgt.    No. per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name <b>Micah T. Reynolds, Technology Sciences Group, Inc.</b>	Title <b>Senior Regulatory Consultant</b>	Telephone No. (Include Area Code) <b>(202) 828-8967</b>
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received <b>(Stamped)</b>
2. Signature 		
3. Title <b>Regulatory Consultant to Veltek Associates, Inc.</b>		
4. Typed Name <b>Micah T. Reynolds</b>		5. Date <b>October 8, 2013</b>



**Technology Sciences Group Inc.**  
1150 18<sup>th</sup> Street, Suite 1000  
Washington, DC 20036  
Direct: (202) 828-8967  
Fax: (202) 872-0745  
E-Mail: MReynolds@TSGUSA.com

**Micah T. Reynolds**  
Senior Regulatory Consultant

October 8, 2013

**Veltek Associates, Inc.**  
**Submission of Label Notification for**  
**DECON-AHOL Aerosol; EPA Reg. No. 68959-1**

Mr. Marshall Swindell (PM-33)  
Antimicrobials Division (7510P)  
Office of Pesticide Programs (NOTIF)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202

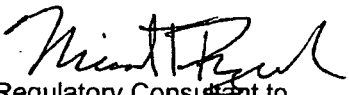
Dear Marshall:

Technology Sciences Group, Inc., on behalf of Veltek Associates, Inc. (Veltek), is submitting the enclosed label notification for the above referenced product. The changes being made in the enclosed label are the addition of alternate brand names, additional text specific to the container to be used, revision and addition of label reference statements, and addition of select of non-FIFRA language. These statements are similar to its sister product, STER-AHOL Aerosol (EPA Reg. No. 68959-3). Please find enclosed the following documents supporting this notification:

- 1) EPA Notification Form (EPA Form 8570-1);
- 2) One redline copy of the proposed label with changes indicated;
- 3) Three (3) clean copies of the proposed label.

If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8967 or by e-mail at [mreynolds@tsgusa.com](mailto:mreynolds@tsgusa.com).

Sincerely,

  
Regulatory Consultant to  
Veltek Associates, Inc.

Enclosures  
CC: P. Deschenes (Veltek)

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**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<sup>®mc</sup> 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]**

**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

**NOTIFICATION**  
 Date Reviewed: 9/18/13  
 Reviewed By: [Signature]

**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.

517

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**

<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.</li> <li>• Call poison control center or doctor for treatment advice.</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Move person to fresh air.</li> <li>• Do not induce vomiting unless told to by a poison control center or doctor.</li> <li>• Do not give anything to an unconscious person.</li> <li>• Have product container or label with you when calling a poison control center or doctor, or going for treatment.</li> </ul>
<b>If inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>• Call poison control center or doctor for treatment advice.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15 – 20 minutes.</li> <li>• Call poison control center or doctor for treatment advice.</li> </ul>
<p>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.</p>	

**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.

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**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.

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### 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:

