

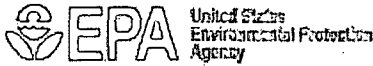
68959-4

12/27/2012

Page 1 of 6

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

DEC 27 2012



Office of Pesticide Programs

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

RECEIVED
33 Jan 2013
D. Dechenew

Attention: Micah T. Reynolds

Subject: DECON-AHOL Aerosol
EPA Registration No. 68959-4
Notification Dated November 26, 2012

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9).

Proposed Notification

- To Correct Typographical Errors
- To Add Modify front Panel Reference Statement

General Comments

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

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely

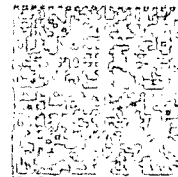
Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510P)



United States
Environmental Protection
Agency
Washington, DC 20460

Official Business
Penalty for Private Use

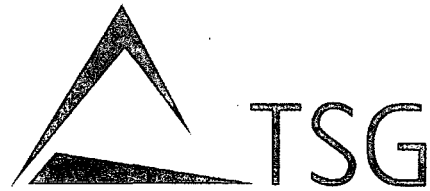
WILL STOP 7510P



Post or

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01/18/2013
United States 20460
US POSTAGE

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

Micah T. Reynolds
Regulatory Consultant

November 26, 2012

Veltek Associates, Inc.
Submission of Label Notification for
DECON-AHOL Aerosol; EPA Reg. No. 68959-4

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

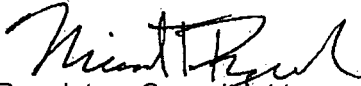
Dear Marshall:

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 primary typographical in nature. The word "Explosive" has been a remnant from the initial registration filing for this product and is an inappropriate descriptor of the physical properties of this product. This product is not explosive in nature and is supported accordingly by its submitted physical/chemical properties data. Its sister product, DECON-AHOL (EPA Reg. No. 68959-2), is the liquid version of the same formulation and itself is not explosive in nature. The enclosed label already contains appropriate precautionary text based on a pressurized or aerosol container. Accordingly, this label change is submitted to simply align both products' hazard labeling. 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.

Sincerely,


Regulatory Consultant to
Veltek Associates, Inc.

Enclosures
CC: P. Deschenes (Veltek)

Washington, D.C.
1150 18th St., NW, Suite 1000
Washington, D.C. 20036
Phone: (202) 223-4392


California
712 Fifth St., Suite A
Davis, CA 95616
Phone: (530) 757-1245

Canada
275 Slater St., Suite 900
Ottawa, Ontario K1P 5H9
Phone: (613) 247-6285

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Please read instructions on reverse side before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

	United States Environmental Protection Agency 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 68959-4	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) DECON-AHOL Aerosol	PM# 33	
5. Name And Address Of Applicant (Include ZIP Code) Veltek Associates, Inc. 15 Lee Boulevard Malvern, PA 19355-1234		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.)

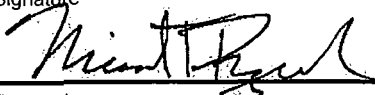
Submission of Label Notification to correct typographical errors and add modify front panel reference statement.

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, 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	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Pager glued <input type="checkbox"/> Stenciled		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Micah T. Reynolds, Technology Sciences Group, Inc.	Title Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8967
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 (Stamped)
2. Signature 		3. Title Regulatory Consultant to Veltek Associates, Inc.
4. Typed Name Micah T. Reynolds		5. Date November 26, 2012

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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

DECON-AHOL^{®mc} AEROSOL
WFI Formula

(Gamma Irradiated)

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)

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

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

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.
<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.

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.

6 7 6

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 and 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.