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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:

68959-2

Date of Issuance:

JAN 27 2010

Term of Issuance:

Conditional

Name of Pesticide Product:

DECON-AHOL

NOTICE OF PESTICIDE:

[x] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

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

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration 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/reregistered 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 conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
a. Revise the "EPA Registration Number to read, "EPA Reg. No. 68959-2".

Signature of Approving Official:

Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date:

JAN 27 2010

b. Add instructions to the "Pesticide Storage" section that specify what to do if the product leaks or spills from its container.

c. Under the "Container Disposal" section, change the container language to read:

Non-refillable container. Do not reuse this container to hold materials other than pesticides or diluted pesticides (rinsate). Offer for recycling for available or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities.

RESIDUE REMOCAL INSTRUCTIONS: (For containers less than 5 gallons)
Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: 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 procedure two more times.

RESIDUE REMOVAL INSTRUCTIONS: (For containers greater than 5 gallons)
Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times.

d. Revise the "Precautionary statements" to read:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Harmful if swallowed or inhaled. Causes irreversible eye damage. 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 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.

e. In the First Aid Statements, include the following paragraphs directly below the "If swallowed:" section.

"Have the product container or label with you when calling a poison Control center or doctor or going for treatment."

"For emergency information on {product, use, etc.}, call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM Pacific Time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222."

f. Remove the term "sterile" from the proposed label.

g. Identify types of surfaces on which the product may be used (e.g., stainless steel, chrome, glass, vinyl).


h. Refer to the enclosed copies of the Efficacy and Product Chemistry reviews for further comments.

4. Submit two (2) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the "accepted" label is enclosed for your records.

Sincerely,


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

Enclosures

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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

[FRONT PANEL]

DECON-AHOL
WFI Formula

(Gamma Irradiated)

For Use in Clean Rooms and Controlled Areas

Hard Surface Disinfectant and Sanitizer

Active Ingredients:
 Isopropyl Alcohol CAS# 67-63-070.0%
Other Ingredients:
 USP Water for Injection..... 30.0%
Total:..... 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER – FLAMMABLE

Keep away from heat or open flame.
 Store at room temperature below 48.8°C (120°F)

See other panel for first aid and additional precautions
 See container for lot number and storage expiration date

US EPA Reg. No.: 68959-E
US EPA Est. No.: 68959-PA-001
Canadian DIN: xxxxxx

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

In Canada: Distributed by:
 Canada Clean Room
 280 Terance Mathews
 Kanata¹ On. K2M 2C6
 Inquiries: (888) 595-8070

ACCEPTED
 with **COMMENTS**
 EPA Letter Dated:

JAN 27 2010

*Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No.*

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

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| FIRST AID | |
|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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. |
| 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 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 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. |

[BACK / SIDE PANELS]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Not for personal use. Not for use on or around food. Do not get on skin or in eyes. Do not take internally and do not inhale vapor.

PHYSICAL AND CHEMICAL HAZARDS: This product may be irritating to the eyes, skin, gastrointestinal tract and respiratory system. May cause central nervous system depression. Flammable liquid and vapor. Vapor may cause flash fire. Keep away from heat, sparks, direct sunlight, 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.

PERSONAL PROTECTIVE EQUIPMENT: Wear eye protection goggles or face shield. Wear chemical-resistant gloves. Use supplied air respirators if levels exceed OSHA PEL.

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 without having obtained the U.S. label at the time of purchase and following the U.S. label at the time of application.
- 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. The user assumes the risk to persons or property that arises from any such use of this product.

USE: Disinfects and sanitizes cleanrooms and controlled areas such as those used in healthcare institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. May be used to disinfect hard, inanimate surfaces in aseptic filling *[note to reviewer: aseptic filling rooms are sterile environments where pharmaceutical products are produced and bottled]* and gowning rooms *[note to reviewer:*

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with COMMENTS
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gowning rooms are rooms where the employees involved with manufacturing pharmaceuticals put on sterile gowns, hair nets, booties, gloves, etc to prevent contamination in the clean/aseptic processing rooms], general manufacturing areas, or on machinery [note to reviewer: the machinery is usually stainless steel and requires disinfection in clean/aseptic processing rooms, tools [note to reviewer: the tools here are things to help service the equipment during aseptic filling and production of pharmaceuticals], tables, counters, laminar flow benches, floors, walls, carts, shelves and glass. It is compatible with most hard surface materials.

DISINFECTION: Use this product while wearing personal protection such as eye protection and chemical-resistant gloves. Use with adequate ventilation and spray away from eyes and face. DECON-AHOL is ready to use. Do not dilute. 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 and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 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 the presence of fetal bovine serum organic load in 10 minutes.

SANITIZATION: For Use on hard, non-porous environmental 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 is an effective sanitizer on inanimate, non-food contact surfaces against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella pneumoniae* (ATCC#4352) in the presence of fetal bovine serum organic load 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: Pesticide 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. Never place unused product down any indoor or outdoor drain.

Container Disposal: Non-refillable container. Do not reuse or refill this container Do not puncture container and do not incinerate container. Offer for recycling, or dispose of in a sanitary landfill.

FIRST RESPONDERS – For Spill/Exposure Emergency Response Service in English (and 26 languages) +44 208 762 8322, Arabic +961 3 487 287, Chinese +86 10 5100 3039. Calls originating from the USA or Canada prefix (+) with 011.

Lot number/ Batch Code: XXXXX

EXPIRY: day/MONTH/year. Once opened use within XXX

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