

68959-2

11/22/2011

10/5



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Heather R. Bjornson
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Washington, D.C. 20036

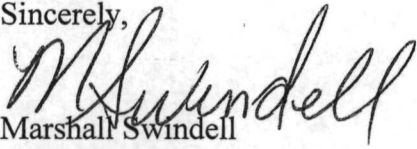
NOV 22 2011

DECON-AHOL NAFTA Label
EPA Registration Number 68959-2
Your Submission Dated November 9th, 2011
EPA Received Date November 9th, 2011

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to review the product labeling under the NAFTA labeling process, is acceptable.

A stamped copy of the product labeling is enclosed.

If you have any questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,

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

2015

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}
WFI Formula

(Gamma Irradiated)

For Use in Clean Rooms and Controlled Areas

Hard Surface Disinfectant

Active Ingredients:

Isopropyl Alcohol CAS# 67-63-070.0%

Other Ingredients:

*Water30.0%

Total:..... 100.0%

*USP Water for Injection

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

US EPA Reg. No.: 68959-2
US EPA Est. No.: 68959-PA-001
Canadian DIN: 02351374

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

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

ACCEPTED
with COMMENTS
EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 68959-2

Net Contents: (In Canada XXXX mL or litres) (In US XXX 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. • Have product container or label with you when calling poison control 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 a 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: 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 central nervous system depression.

PHYSICAL AND CHEMICAL HAZARDS: Flammable liquid and vapor. Keep away from heat or open flame. Exposure to temperatures above 48.8°C (120° F) may cause bursting. Do not mix this product with other chemicals including: acids, oxidizing materials, combustible materials, halogenated hydrocarbons, peroxides, bases and metal salts.

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

REGISTERED INSECTICIDE,
 UNDER THE FEDERAL INSECTICIDE,
 FUNGICIDE, AND RODENTICIDE ACT AS
 AMENDED, FOR PESTICIDE,
 REGISTERED UNDER EPA REG. NO. 68959-2

ACCEPTED
 WITH COMMENTS
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4095

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 clean rooms and controlled areas such as 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, 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 of face shield, protective clothing and chemically 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 6-8 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: Use 5 minute contact time on hard, non-porous surfaces (made from: stainless steel, glass, Corian™, laminate flooring, aluminum, pvc, mild steel, polypropylene), in isolators, clean rooms, 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). Absorb spills with inert dry absorbent or sand. Absorb spills with inert material (e.g., dry sand or earth), 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 this container to hold materials other than pesticides or diluted pesticides (rinsate). 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 flow begins to drip. Repeat two more times.][[(for containers greater than 5 gallons) Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container on its other 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.

ACCEPTED
with COMMENTS
EPA Letter Dated:
NOV 22

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 48959-2

Veltek Associates – DECON-AHOL (pending as EPA Reg. No. 68959-2) NAFTA Label version (5) dated November 14, 2011

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 (90 Days)

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