

56753-1

02/04/2013

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U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Antimicrobials Division (7510P)
 1200 Pennsylvania Avenue NW
 Washington, D.C. 20460

EPA Reg. Number: **56753-1**
 Date of Issuance: **FEB 04 2013**

Term of Issuance:
Conditional

Name of Pesticide Product:
CIDEHOL ST

NOTICE OF PESTICIDE:
 Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Decon Labs, Inc.
 460 Glennie Circle
 King of Prussia, PA 19406

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 unconditionally registered in accordance with FIFRA sec 3(c)(5) 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. 56753-1"
3. Submit a 1 year Storage Stability and a 1 year Corrosion Characteristics study, both of which must include data at 0, 3, 6, 9 and 12 months.

Signature of Approving Official:

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

Date:

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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 label is enclosed for your records. Submit one (3) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Elizabeth Hernandez at (703) 347-0241.

Sincerely,



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

Enclosure: (Stamped Label)

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ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 04 2013

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

56753-1

CiDehol® ST

(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.: 56753-1

US EPA Est. No.:

Manufactured by:

Decon Labs, Inc.

460 Glennie Circle

King of Prussia, PA 19406

Net Contents: In US XXX oz or gallons

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FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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. • 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 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.
Have product container or label with you when calling poison control or doctor, or going for treatment.	
<p>For emergency information on CiDehol® ST, call the National Pesticides Information Center at 1-800-858-7378, 6:30-4:30 pm Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.</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.

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, halogens, peroxides, bases and metal salts.

DIRECTIONS FOR USE

Read the label before using

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

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.

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Fungicide, and Rodenticide Act,
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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 or face shield, protective clothing and chemically resistant gloves. Use with adequate ventilation and spray away from eyes and face. *CiDehol® ST* is ready to use. Do not dilute. Pre-clean surface or item of heavy soil or gross filth before application. Hold container upright 6-8 inches from surface. Spray product on surface 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.

CiDehol® ST is bactericidal. The results of AOAC Efficacy Tests show that *CiDehol® ST* is an effective hard surface disinfectant against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC#6538), and *Salmonella enterica* (ATCC#10708) in the presence of 5% 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.

CiDehol® ST is an effective sanitizer on inanimate, non-food contact surfaces against *Staphylococcus aureus* (ATCC#6538) and *Enterobacter aerogenes* (ATCC#13048) in the presence of 5% 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 acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate 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 Disposal: Non-refillable container. Do not reuse this container to hold materials other than pesticides or diluted pesticides (rinsate). Triple rinse (or equivalent). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state. Offer for recycling if available or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.

Lot number/ Batch Code: XXXXX
EXPIRY: MONTH/YEAR.