

56753-2

4/18/2013

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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:
56753-2

Date of Issuance:
APR 18 2013

Term of Issuance:
Unconditional

Name of Pesticide Product:

SANIHOL 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 (OPP Decision No. D-471498) 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.

Signature of Approving Official:

Jacqueline Campbell
Jacqueline Campbell, McFarlane
Product Manager Team-34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date:

APR 18 2013

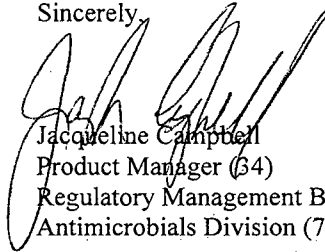
Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

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

If these conditions are not complied with, this 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.

If you have questions concerning this matter, please contact Jaclyn Pyne at (703) 347-0213 or by email at pyne.jaclyn@epa.gov.

Sincerely,



Jacqueline Campbell
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: Stamped Label

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SANIHOL® ST

(Gamma Irradiated)

For Use in Clean Rooms and Controlled Areas

Hard Surface Disinfectant and Sanitizer

Active Ingredients:

Ethyl alcohol	63.4%
*Other Ingredients	36.6%
Total:	100.0%

*Ethyl alcohol is denatured with methyl alcohol and isopropyl alcohol; contains less than 3.5% methyl alcohol; contains USP Water for Injection

KEEP OUT OF REACH OF CHILDREN

WARNING – FLAMMABLE

Keep away from heat or open flame.

Store at room temperature below 48.8°C (120°F)

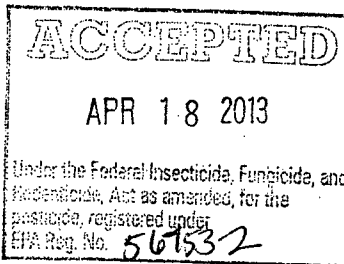
See other panel for first aid and additional precautions

US EPA Reg. No.: 56753-2

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

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 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.
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.
<p>Have product container or label with you when calling poison control or doctor, or going for treatment.</p> <p>For emergency information on SANIHOL® 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

WARNING: Causes substantial but temporary eye injury. Harmful if absorbed through the skin or inhaled. Do not get in eyes, skin, or on clothing. Avoid breathing vapor or spray mist. Wear goggles or safety glasses and chemically resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco and or using the toilet. Remove and wash contaminated clothing before reuse.

PHYSICAL AND CHEMICAL HAZARDS: 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.

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.

USE: Disinfects and sanitizes clean rooms and controlled areas such as those used in healthcare institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. This product may be used to disinfect non-food contact, non-porous, inanimate, hard surfaces in areas such as: aseptic filling and gowning rooms, general manufacturing areas and laboratories. It may be used on surfaces, such as: 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: Wear personal protection such as eye protection goggles or face shield. Wear chemical-resistant gloves. Use with adequate ventilation and spray away from eyes and face. If you experience eye watering, headaches or dizziness discontinue aerosolizing and inhaling fumes. *SANIHOL*[®] ST 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 *SANIHOL*[®] ST 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. Do not replace excess product into original container after use or after removal from original container, even if it was not used.

SANIHOL[®] ST is bactericidal. The results of AOAC Efficacy Tests show that *SANIHOL*[®] ST is an effective hard surface disinfectant against *Pseudomonas aeruginosa* (ATCC# 15442) and *Staphylococcus aureus* (ATCC#6538) in the presence of 5% fetal bovine serum organic load in 10 minutes.

SANITIZATION: Follow all disinfection directions and allow to remain wet for a minimum of 5 minutes.

SANIHOL[®] 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.

Pesticide Storage: Store in the original container in a dry cool place below 48.8°C (120° F).

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

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.

Reagent Alcohol: Specially Denatured Alcohol Formula 3A 95 parts by volume and isopropyl alcohol 5 parts by volume.

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