



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

EPA Reg. Number:

1043-133

Date of Issuance:

4/12/19

NOTICE OF PESTICIDE:

Registration  
 Reregistration  
 (under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Septihol®Ethyl WFI st Alcohol Solution

Name and Address of Registrant (include ZIP Code):

STERIS Corporation  
 7501 Page Avenue  
 St. Louis, MO 63133

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials 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 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 section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 1043-133."

Signature of Approving Official:

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

Date:

4/12/19

3. Submit one copy of the revised final printed label for the record before you release the product for shipment.


Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSF:

- Basic Confidential Statement CSF dated 09/11/2018

If you have any questions, please contact Lorena Rivas by phone at (703) 305-5027, or via email at [rivas.lorena@epa.gov](mailto:rivas.lorena@epa.gov)

Sincerely,

A handwritten signature in red ink that reads "Jacqueline Hardy". The signature is written in a cursive style and is positioned above the typed name.

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

Enclose: Accepted Stamped Label  
Product Chemistry Review dated 03/12/2019

# Septihol<sup>®</sup> Ethyl WFI st Alcohol Solution

Reorder Number: XXX

Net Contents: XXX

**[Gamma Irradiated] [Sterile]**

**Disinfectant • Fungicide**

INTENDED FOR INDUSTRIAL AND INSTITUTIONAL USE

**Active Ingredients:**

Ethanol ..... 55.39%

**Other Ingredients:** ..... 44.61%

**Total:** ..... 100.00%

EPA Reg. No. 1043-XXX [EPA Est. No. 1043-MO-2]

**KEEP OUT OF REACH OF CHILDREN**

**WARNING - FLAMMABLE**

Keep away from heat and open flame.

**ACCEPTED**

**04/12/2019**

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 1043-133

**FIRST AID**

If in Eyes	<ul style="list-style-type: none"><li>•Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>•Call a poison control center or doctor for treatment advice.</li></ul>
If Swallowed	<ul style="list-style-type: none"><li>•Call poison control center or doctor immediately for treatment advice.</li><li>•Have person sip one or two glasses of water if able to swallow.</li><li>•Do not induce vomiting unless told to do so by the poison control center or doctor.</li><li>•Do not give anything by mouth to an unconscious person.</li></ul>
If on Skin or Clothing	<ul style="list-style-type: none"><li>•Take off contaminated clothing.</li><li>•Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>•Call a poison control center or doctor for treatment advice.</li></ul>
If Inhaled:	<ul style="list-style-type: none"><li>•Move person to fresh air.</li><li>•If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferable mouth to mouth, if possible.</li><li>•Call a poison control center or doctor for further treatment.</li></ul>
HOT LINE NUMBER 1-800-424-9300	
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	

See [side panel] [back panel] [insert] for additional precautionary statements [and] [or] [directions for use].

[Brackets denote optional text.]

Product Made in U.S.A.

STERIS Corporation  
7501 Page Ave.  
St. Louis, MO 63133 U.S.A.  
1-800-548-4873

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**WARNING:** Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear such as goggles or safety glasses Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, 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:** **Flammable** liquid and vapor. Keep away from heat or open flame. Do not mix this product with other chemicals including: acids, oxidizing materials, halogens, peroxides, bases and metal salts.

Septihol® Ethyl WFI st Alcohol Solution is intended for use in institutions such as pharmaceutical plants, medical device manufacturers, veterinary clinics and other hard, non-porous surfaces where disinfection, cleaning and deodorizing are a necessity.

Septihol® Ethyl WFI st Alcohol Solution is effective in the presence of organic soil (5% blood serum) on hard, non-porous surfaces and may be used for easy cleaning and disinfecting of all washable hard, non-porous environmental surfaces such as floors, walls, woodwork, bathroom fixtures, equipment and furniture. It may be used for cleaning and disinfecting chrome, stainless steel, glazed porcelain, glass, tile, non-porous washable painted or varnished surfaces, as well as resilient vinyl, linoleum, sealed terrazzo or other combination type floors.

**DISINFECTANT:** This product was tested using the A.O.A.C. Germicidal Use-Dilution Test against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442) and it passed in the presence of 5% organic soil (serum), 10 minutes at 20°C.

**FUNGICIDAL:** This product was tested using the A.O.A.C Fungicidal Test against *Trichophyton interdigitale* (ATCC 9533) and it passed in the presence of 5% organic soil (serum) in 5 minutes at 20°C

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.  
This product is not for use on medical device surfaces.

**CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES:** Before cleaning begins, always sweep or dust mop area to be cleaned thoroughly, removing any gross filth. Apply solution with a cloth, sponge, mop, brush or by coarse spray using normal cleaning methods. Allow treated surfaces to remain wet for 10 minutes, then remove excess solution with a wrung-out applicator. This is a complete, ready-to-use product. Do not add or dilute with other chemicals. Use only as directed.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE:** Do not store near heat or open flame. If frozen, thaw and re-mix before use.

**PESTICIDE 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 HANDLING:

(For ≤5 gal:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or dispose in sanitary landfill or by other procedures approved by state and local authorities. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[Sterile unless packaging is compromised.]

[Brackets denote optional text.]