U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Antimicrobials Division (7510P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460 NOTICE OF PESTICIDE: <u>X</u> Registration Reregistration	EPA Reg. Number: 1043-132 Term of Issuance: Unconditional	Date of Issuance:	
(under FIFRA, as amended)	Name of Pesticide Product: Septihol st Alcohol Solution		
Name and Address of Registrant (include ZIP Code): Steris Corporation 7501 Page Ave 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/rergistration/registration review of your product when the Agency requires all registrants of similar products to submit such data. 2. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data. 			
Signature of Approving Official: Zeno Bain, Acting Product Manager 33	Date:		
Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs EPA Form 8570-6			

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- 3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 1043-132."
- 4. 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 CSFs:

• Basic CSF dated 06/26/2018

If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at <u>heffernan.aline@epa.gov</u>.

Enclosure: Stamped Label

Septihol[®] st Alcohol Solution

Reorder Number: XXX

Net Contents: XXX

[Gamma Irradiated] [Sterile unless package is open or compromised] Germicide* • Fungicide

INTENDED FOR INDUSTRIAL AND INSTITUTIONAL USE

Active Ingredients: Isopropyl Alcohol, USP** Other Ingredients:	63.60%
Purified Water, USP	36.40%
Total: ** Isopropyl Alcohol, USP 70.0% by volume.	100.00%

ACCEPTED Dec 17, 2018

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 1043-132

EPA Reg. No. 1043-XXX [EPA Est. No. 211-KS-001] [EPA Est. No. 1043-MO-2] [EPA Est. No. 11563-MI-1]

KEEP OUT OF REACH OF CHILDREN WARNING **FLAMMABLE**

Keep away from heat and open flame.

	FIRST AID
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. Call a poison control center or doctor for treatment advice.
If swallowed	 Call 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 do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
If on skin or clothing	 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 inhaled	 •Move person to fresh air. •If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. •Call a poison control center or doctor for further treatment advice.
	HOT LINE NUMBER: 800-548-4873
Have the product conta treatment.	ainer or label with you when calling a poison control center or doctor, or going for

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.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on skin or clothing. Wear protective eyewear such as goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using toilet. Remove and wash contaminated clothing before reuse.

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® st Alcohol Solution is intended for use in institutions such as pharmaceutical plants, medical device manufacturers, veterinary clinics and other indoor areas where disinfection, cleaning and deodorizing are a necessity. Septihol® 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, sealed woodwork, bathroom fixtures, equipment and furniture. It may be used for cleaning and disinfecting chrome, stainless steel, other metal surfaces, porcelain, glass, tile, washable painted or varnished surfaces, as well as resilient vinyl, asphalt, linoleum, terrazzo or other combination type hard, non-porous floors.

***GERMICIDAL:** When tested against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442), it passes the A.O.A.C. Germicidal Use-Dilution Test, in the presence of 5% organic soil (serum), 10 minutes at 20°C. When tested against *Trichophyton interdigitale* (ATCC 9533), it passes the A.O.A.C. Fungicidal Test in the presence of 5% organic soil (serum) in 5 minutes at 20°C.

FUNGICIDAL: When tested against *Trichophyton interdigitale* (ATCC 9533), it passes the A.O.A.C. Fungicidal Test 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.

CLEANING WASHABLE, HARD, NON-POROUS SURFACES: Before cleaning begins, always sweep or dust mop area to be cleaned thoroughly, removing any gross filth.

DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES: Before disinfection 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 product. Do not add or dilute with other chemicals. If frozen, thaw and remix before use. 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.

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 1/4 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.]