

70467-3

6-3-1105

1/5

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

EPA Reg.  
Number:

70467-3

Date of Issuance:

June 3, 2005



NOTICE OF PESTICIDE:

Registration  
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

BioSurf

Name and Address of Registrant (include ZIP Code):

Micrylium  
2421 Hyde Park Blvd.  
Niagra Falls, NY 14305

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 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 reregistration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

- a. Add the phrase "EPA Registration Number 70467-3".
- b. The Precautionary statements must be revised to read as follows:

**Precautionary Statements**  
Hazards to Humans and Domestic Animals  
**Caution**

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or, using tobacco.

Signature of Approving Official:

Adam Heyward  
Product Manager Team-34  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

Date:

June 3, 2005

- c. Delete the word "**Flammable**" from the precautionary statement. The statement must be listed in a separate section as follows:

**PHYSICAL OR CHEMICAL HAZARDS**

Flammable. Keep away from heat and open flames.

- d. The First Aid Statement must be revised to read as follows:

**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. Call a Poison Control Center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact (toll-free number if available) for emergency medical treatment information.

Refer to PR Notice 2001-1 for detailed information.

- e. Delete the term "Full Strength Formulation," or "Full Strength" wherever it appears on the label. The statement implied heightened efficacy of the pesticide by itself or as compared with another product.
- f. The microorganism ATCC numbers must be listed next to the microorganism on the label.
- g. The hospital terminal sterilant/high-level disinfectant statement must be separated from the other text in the section.
- h. The Storage & Disposal statement must be revised to read as follows:

**STORAGE & DISPOSAL**

Do not reuse container (bottle, can, jars). Rinse thoroughly before discarding in trash.

Refer to PR Notice 83-3 for detailed information.

3. Submit three (3) copies of the final printed label prior to releasing this product for sale.

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.

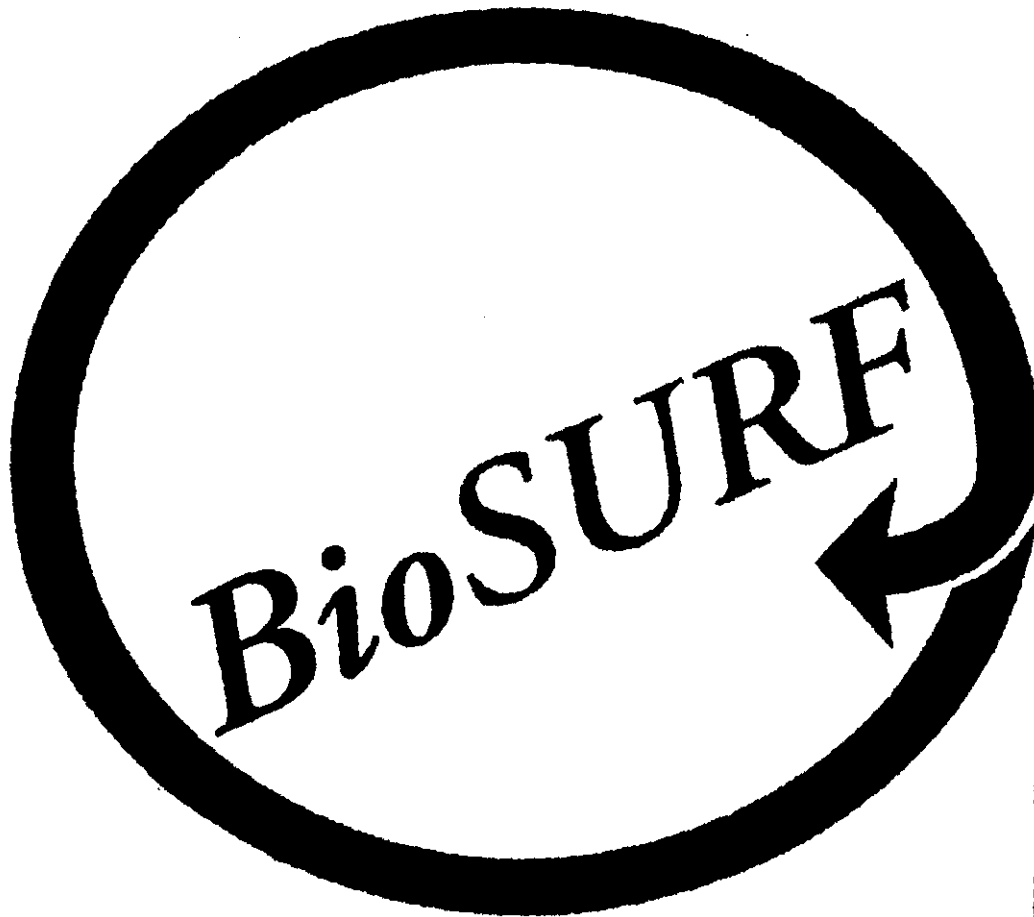
Sincerely,



Adam Heyward  
Product Manager 34  
Regulatory Branch II  
Antimicrobials Division (7510C)

Enclosure: (Stamped Labeling)

4/3



16.9 fl oz  
500 ml

EPA Registration Number 70467-3  
EPA Establishment 070467-CAN-001

Micrylium  
ISO 9001 : 2000

**Hospital Hard Surface Disinfectant**  
**BioSURF is a ready to use hard surface disinfectant**  
**for nonpourous surfaces • One Step**

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

JUN - 3 2005

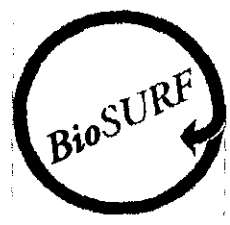
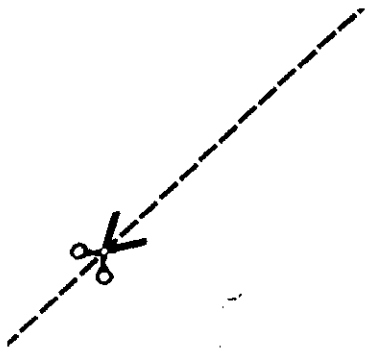
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
recommended, for the pesticide,  
registered under EPA Reg. No. **70467-3**

Active Ingredients	
Ethanol	70.5%
Chlorhexidine Gluconate	0.2%
Other Ingredients	29.3%
Total	100.0%

**Tuberculocidal - Parvovirucidal in 50 seconds**  
**Pseudomonacidal in 20 seconds**

**CAUTION • READ PRECAUTIONS ON BACK PANEL • KEEP OUT OF THE REACH OF CHILDREN**  
**FLAMMABLE • PRECAUTIONARY STATEMENT HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

5/5

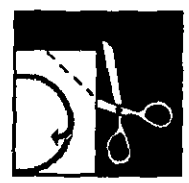


Aldehyde • NPE • Phenol Free

**BioSURF** is a full strength, ready to use environmental hard surface disinfectant for nonporous surfaces

Instructions for use

It is a violation of Federal law to use this product in a manner inconsistent with its labelling. **BioSURF** kills Tuberculosis (*Mycobacterium bovis BCG*) and is Virucidal (*Canine parvovirus CPV-265*) in under one minute in the presence of 5% bioburden. To effectively kill bacteria, fungi and inactivate viruses use **BioSURF** full strength. Remove trigger from 24 fl oz spray bottle. Cut this 16.9 fl oz refill pouch along the dotted line with scissors. Use a clean funnel to fill or refill bottle. Replace the trigger and rinse funnel. **BioSURF** is to be used on all countertops and metal surfaces. May be used on wheelchairs, metal bed frames, and toilets. Spray all areas with a light mist. Maintain wetness for one minute, then wipe with disposable paper towels or "Le Cloth™" towelettes.



Enhancing dentistry with education and technology™

www.zenithdental.com  
Englewood, NJ 07631  
1-800-662-6383



PROFESSIONAL DISINFECTION

www.micrylium.com  
Niagara Falls, NY 14301 • Toronto, Canada  
1-800-489-8868

Precautionary Statements

**PHYSICAL OR CHEMICAL HAZARDS:** Flammable. Keep away from heat and open flames. Keep out of the reach of Children. DO NOT use on alcohol sensitive materials such as hot plastic casings, acrylic paint, styrene or disposable plastic items. Do not apply this product in or on electrical equipment due to the possibility of shock hazard. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. This product is not a dermal sensitizer. 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. **FIRST AID:** If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses after the first 5 minutes and continue rinsing. Call a Poison Control Center or doctor for treatment advice. If ingested, do not induce vomiting. Drink large quantities of milk or water. **STORAGE & DISPOSAL:** Do not store near open flame, at elevated temperature or in intense light. Dispose of any packaging or product materials in domestic waste. **ENVIRONMENTAL HAZARDS:** None

PR 83-3