

70467-3

10/7/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT - 7 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Mr. David Swain  
Agent for Micrylium Laboratories  
SRC Scientific & Regulatory Consultants, Inc.  
P.O. Box 1014  
Columbia City, IN 46725

Subject: BioSurf  
EPA Registration No.: 70467-3  
Notification Date: September 7, 2010  
EPA Receipt Date: September 8, 2010

Dear Mr. Swain,

This letter acknowledges receipt of your notification under the provisions of FIFRA section 3(c)9 and PR Notice 2007-4.

**Proposed Notification**

Revised Container Disposal Statements in accordance with PR Notice 2007-4

**General Comments**

Based on a review of the submitted materials, your notification to revise the container disposal statements per PR Notice 2007-4 is acceptable and apart of the records on file.

Should you have any questions regarding this letter, please contact me by telephone at (703) 308-6416 or by email at [Campbell-mcfarlane.jacqueline@epa.gov](mailto:Campbell-mcfarlane.jacqueline@epa.gov) or Glen McLeod by telephone at (703) 347-0181 or by email at [mcleod.glen@epa.gov](mailto:mcleod.glen@epa.gov).

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

**CONCURRENCES**

SYMBOL							
SURNAME							
DATE							

Please read instructions on reverse before completing form.

Form Approved JMB No. 2070-0060. Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 70467-3	2. EPA Product Manager J. Campbell-MacFarlane	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BIOSURF	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Micrylium Laboratories 3309 Filmore Street, Suite A San Francisco, CA 94123 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Notification of updated storage and disposal language per PR Notice 2007-4. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Please contact David Swain for questions and provide an electronic response to dswain@srccconsultants.com or at 260-244-6273 (fax).

### Section - III

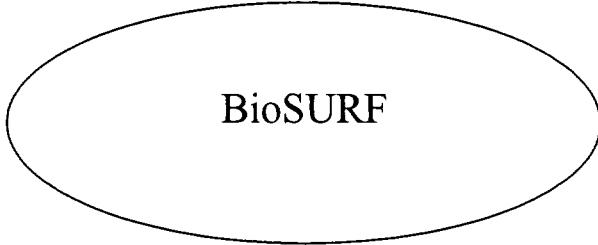
1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2 fl. oz. 16.9 fl. oz. 24 fl. oz. 202 fl. oz.		5. Location of Label Directions <input type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David Swain	Title Agent for Micrylium Laboratories	Telephone No. (include Area Code) (260) 244-6270
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Micrylium Laboratories	
4. Typed Name David Swain	5. Date 9/7/10	



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Net Contents:

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

Micrylium  
ISO 13485 : 2003

**Hospital Hard Surface Disinfectant**

BioSURF is a ready to use hard surface disinfectant for nonporous surfaces • One Step  
[For use on hard, non-porous imaging equipment surfaces]

Active Ingredients

Ethanol	70.5%
Chlorhexidine Gluconate	0.2%
<u>Other Ingredients</u>	29.3%
Total	100.0%

Tuberculocidal – Canine Parvovirucidal  
Pseudomonacidal

**CAUTION**

**READ PRECAUTIONS ON BACK PANEL • KEEP OUT OF THE REACH OF CHILDREN**

**NOTIFICATION**

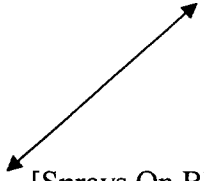
Date Reviewed: 10/2/10  
Reviewed By: G. M. Lead

{Administrative note: any language which appears between { } and is italicized will NOT appear on final printed labels. Any language that appears between [ ] is considered interchangeable language which may appear on final printed labeling}

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BioSURF, 70467-3

BioSURF



[Sprays On Blue Turns Clear!]

Aldehyde • NPE • Phenol Free

BioSURF is a ready to use environmental hard surface disinfectant for nonporous surfaces.  
[Restrooms • Schools • The Office • The Gym • At Home]  
[BioSURF will not stain: Cotton • Nylon • Rayon • Silk • Polyester]

Directions for use

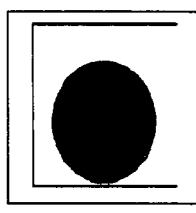
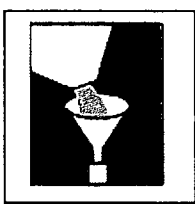
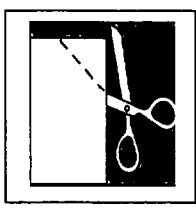
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. BioSURF kills Tuberculosis (*Mycobacterium bovis* BCG) and is Virucidal (Canine parvovirus CPV-265) in [one minute] [60 seconds] in the presence of 5% bioburden. [BioSURF kills *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* (*formally choleraesuis*) in 20 seconds in the presence of 10% bioburden.] [BioSURF kills *Trichophyton mentagrophytes* in 10 seconds in the presence of 10% bioburden.] To effectively kill bacteria, fungi and inactivate canine parvovirus use BioSURF.

{Text for refill package}

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 [This product][is to][can] be used on countertops [and] metal surfaces [and toilet exteriors]. [May be used on wheelchairs, metal bed frames and exteriors of toilets.] [BioSURF may be used on nonporous hard surfaces (imaging equipment, metal, glass, acrylic, and porcelain)]. Spray all areas with a light mist. Maintain wetness for [one minute] [60 seconds] [to kill *Mycobacterium bovis* BCG and Canine parvovirus CPV-265] [.]. [Maintain wetness for 20 seconds to kill bacteria and 10 seconds to kill fungi.] [Blue color disappears,] [then] wipe [away germs] with [disposable paper towel[s]][included towelette][or tissue][or “Le Cloth™ towelettes].

This product is not 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.



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Micrylium Laboratories  
Professional Disinfection  
[www.micrylium.com](http://www.micrylium.com)  
3309 Filmore Street, Suite A  
San Francisco, CA 94123  
1-800-489-8868

Precautionary Statements  
Hazards to Humans and Domestic Animals

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

**PHYSICAL OR CHEMICAL HAZARDS:** Flammable. Keep away from heat or open flame. 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.

**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 1-800-489-8868 for emergency medical treatment information.

**STORAGE & DISPOSAL:**

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

**PESTICIDE STORAGE:** ~~Do not reuse container.~~ Do not store near open flame, at elevated temperature or in intense light.

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

**CONTAINER HANDLING:**

{Nonfillable Containers}: Nonrefillable container. Do not reuse or refill this container. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

{Refillable Containers}: Refillable container. Refill this container with [this brand or brand name] pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. Rinse thoroughly and dispose of any packaging materials in domestic waste. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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