

70467-3

09/15/2006

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

September 15, 2006

Bob MacDonald
Agent for Micrylium Laboratories
SRC, Inc.
P.O. Box 1014
Columbia City, IN 46725

Subject: BIOSURF
EPA Registration No.: 70467-3
Application Date: August 15, 2006
Receipt Date: August 16, 2006

Dear Mr. MacDonald,

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- Addition of the clarifying word 'canine' in front of parvovirucidal.
- Deletion and minor clarification of marketing statements as per the State of California.

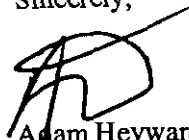
General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422.

Sincerely,



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

CONCURRENCES

YMBOL	7510P						
JRNAME	Graham						
DATE	9/8/06						

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SRC
Scientific & Regulatory
Consultants, Inc.

August 15, 2006

Mr. Adam Heyward, PM 34
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

SUBJECT: BIOSURF
EPA Reg. No.: 70467-3

Dear Adam,

On behalf of our client Micrylium Laboratories, enclosed is a submission for BIOSURF (EPA Reg. No. 70467-3). **This is a notification per PR Notice 98-10. Therefore no PRIA fee is required.**

The primary purpose of this notification is to add/delete minor text dictated by a recent directive from the State of California in their review. Per the state of California, we are clarifying the text "Parvovirucidal" to read "Canine Parvovirucidal", deleting the text "in 50 seconds" "in 20 seconds" and the word "under" before "one minute". We have additionally clarified the virus claim on the back by stating as "canine parvovirus", deleted the word "all" before countertops and inserted "exterior of" before the word toilets. Finally we have added the text "Distributed by:" before Zenith Dental to signify that they are a distributor of the basic registrants and not the manufacture of the Micrylium product. All changes being made are marked by circling the text or area affected & highlighting it in yellow on the Master Label. A clean version of the label is also enclosed without the markings. This notification is consistent with PR Notice 98-10.

Please contact me at (260) 244-6270 or at bmacdonald@srconsultants.com if you have any questions about this notification.

Sincerely,



Bob MacDonald
Agent for Micrylium Laboratories
cc: D. Swift



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 A. Heyward	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 2421 Hyde Park Blvd Niagara Falls, NY 14305-3235 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), 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 text additions through PR Notice 98-10. 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 Bob MacDonald at bmacdonald@srconsultants.com or at 260-244-6273 (fax) with any questions.

Section - III

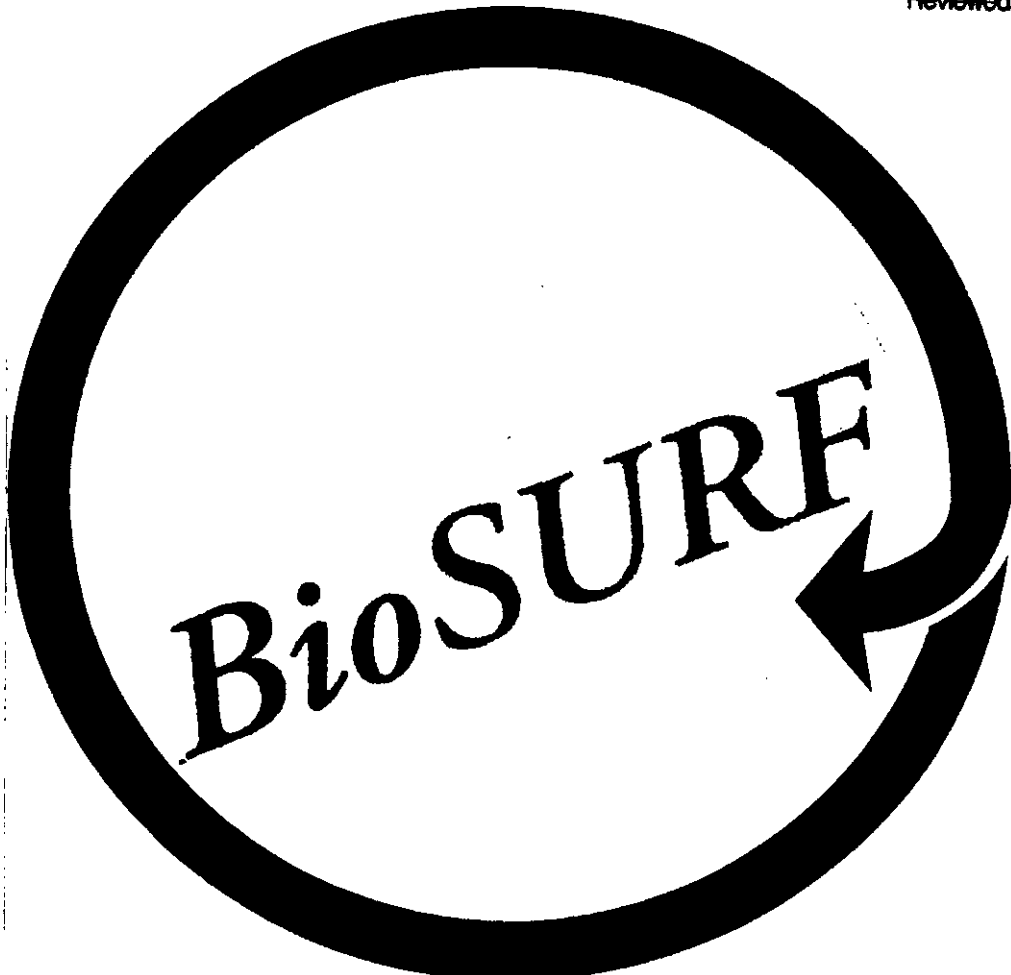
1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product		<input 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 Bob MacDonald	Title Agent for Micrylium Laboratories	Telephone No. (Include Area Code) (260) 244-6270
<p align="center">Certification</p> <p>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.</p>		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Micrylium Laboratories	
4. Typed Name Bob MacDonald	5. Date 8/15/06	

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NOTIFICATION
Date Reviewed: 9-15-04
Reviewed By: A. F. ...



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 nonporous surfaces • One Step

Active Ingredients

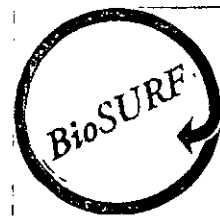
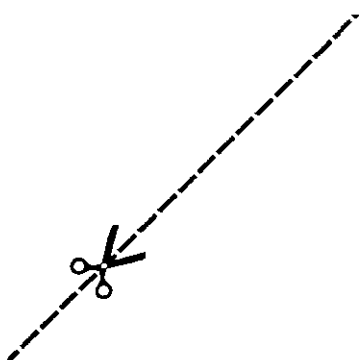
Ethanol	70.5%
Chlorhexidine Gluconate	0.2%
<u>Other Ingredients</u>	29.3%
Total	100.0%

Tuberculocidal - Canine Parvovirucidal
Pseudomonacidal

CAUTION

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

5/10



Aldehyde • NPE • Phenol Free

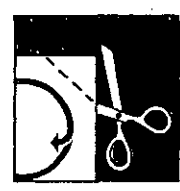
BioSURF is a ready to use environmental hard surface disinfectant for nonporous surfaces

Directions 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 one minute in the presence of 5% bioburden. To effectively kill bacteria, fungi and inactivate *Canine parvovirus* use **BioSURF**.

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 countertops and metal surfaces. May be used on wheelchairs, metal bed frames and exteriors of toilets. Spray all areas with a light mist. Maintain wetness for one minute, then wipe with disposable paper towels or "Le Cloth™" towelettes.

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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.



Distributed by:



Brand Division of Foremost Dental LLC
www.zenithdental.com
Englewood, NJ 07631
1-800-662-6383

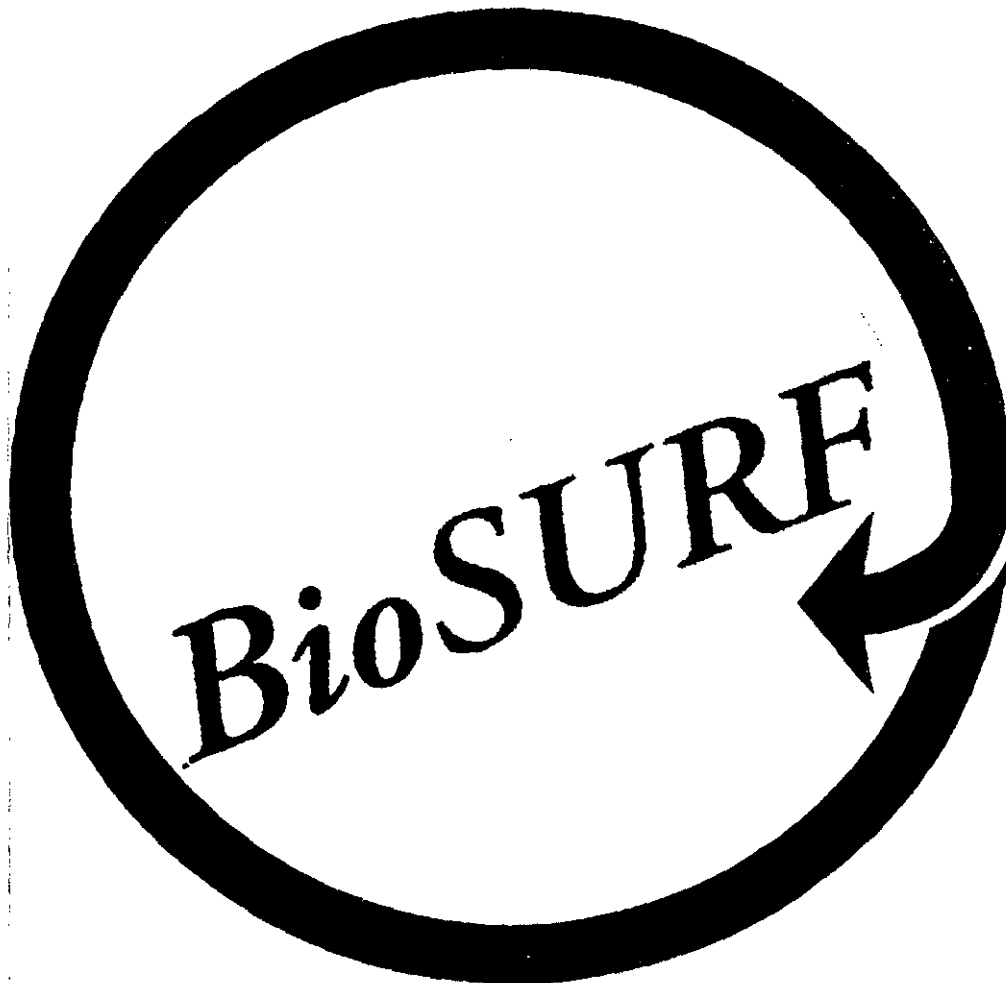


www.micrylium.com
Niagara Falls, NY 14301 • Toronto, Canada
1-800-489-8868

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.
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 reuse container. Do not store near open flame, at elevated temperature or in intense light. Rinse thoroughly and dispose of any packaging materials in domestic waste.

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16.9 fl oz
500 ml

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

Micrylium
ISO 9001 : 2000

Hospital Hard Surface Disinfectant

BioSURE is a ready to use hard surface disinfectant for
nonpourous surfaces • One Step

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