

71094-1

12-4-2007

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

DEC - 4 2007

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

John A. Lopes, Ph.D.
President
Microcide, Inc.
2209 Niagra Dr.
Troy, MI 48083

Subject: Product Name: Pro-San®
EPA Reg. Number.: 71094-1
Application Date: November 5, 2007
Receipt Date: November 15, 2007

Dear Dr. Lopes:

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

Proposed Notification

- Add organisms to label.
- Add acronyms for previously approved organisms.

General Comments

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

The notification application is acceptable with the following comments:

1. Please correct the typo to read 'gram negative' on the second sample label.
2. Delete the term "SUCH AS" from the name of the bacteria.

A copy of the notification has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me by telephone at (703) 308-6422 or by email at heyward.adam@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Adam Heyward", written over a horizontal line.

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

 <p>United States Environmental Protection Agency Washington, DC 20460</p>	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:20px; height:20px;"><input type="checkbox"/></td> <td style="width:20px; height:20px;"><input checked="" type="checkbox"/></td> <td style="width:20px; height:20px;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;">Registration</td> <td style="text-align: center;">Amendment</td> <td style="text-align: center;">Other</td> </tr> </table>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Registration	Amendment	Other	OPP Identifier Number
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
Registration	Amendment	Other						

Application for Pesticide - Section I

1. Company/Product Number 71094-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) PRO-SAN	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) MICROCID, INC. 2209NIAGARA DRIVE TROY, MI 48083 <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. <u>71094-1</u> Product Name <u>PRO-SAN</u>	

Section - II

<input checked="" 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 type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

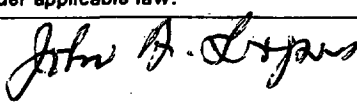
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

A statement of names of organisms to be placed on the label.
 "Such as
 Gram Positive: Staphylococcus aureus;
 Gram Negative : Escherichia coli"

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 checked="" type="checkbox"/> Yes <input 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	If "Yes" Package wgt No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 12 x 0.67 LB (0.3 Kg) Pouches/Box		5. Location of Label Directions <input checked="" type="checkbox"/> On the label	
6. Manner in Which Label is Affixed to Product			<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other <u>Screen Printing</u>		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name John A. Lopes	Title President	Telephone No. (Include Area Code) 243-523-9663
2. Signature 		6. Date Application Received (Stamped)
3. Title President		
4. Typed Name John A. Lopes	5. Date 10/26/2007	
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 both under applicable law.		

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MICROCIDE[®], INC.

Laboratory: 2727 Second Avenue, #334, Detroit, MI 48201, USA.
Office: 2209 Niagara Drive, Troy, MI 48083, USA

Tel & Fax # 248-526-9663

SENT BY CERTIFIED MAIL WITH REQUEST FOR RETURN RECEIPT

November 5, 2007

Mr. Adam Heyward
Product manager
Regulatory Management Branch II
Antimicrobial Division (7510P)
OPP USEPA, 401 M Street S.W.
Washington, D.C. 20460

Ref: Notification for addition of bacterial names
on the label of PRO-SAN, EPA:71094-1

Dear Mr. Adam Heyward:

Please find submission of notification for changes in the label on front panel of pouch label of PRO-SAN, EPA Reg. No: 71094-1.

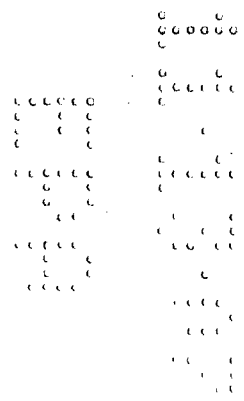
Please find three copies of each label. One additional copy with highlighted change is also enclosed.

1 "Notification of the change in Net Wt Content and EPA establishment number on the label of PRO-SAN, EPA:71094-1 per PR Notice 98-10."

2 "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 the 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."

Thank you
Sincerely,

John A. Lopes, Ph.D.
President
Microcide, Inc.
Tel: 248-526-9663
E-mail: lopes@microcideinc.com



4/6

NOTIFICATION
Date Reviewed: 12-4-07
Reviewed By: *Haruh*

FRONT PANEL OF PRO-SAN LABEL

PRO - SAN®

**Cleaner & Sanitizer for Food Contact Surfaces &
Fruit/Vegetable Wash Powder Concentrate**

ACTIVE INGREDIENTS:

Citric Acid	66.0 %
Sodium dodecylbenzene sulfonate	3.6 %
INERT INGREDIENTS.....	30.4 %
	100.0 %

KILLS 99.999% BACTERIA!

Such As

Gram positive bacteria: *Staphylococcus aureus*

KEEP OUT OF THE REACH OF CHILDREN

DANGER

See back panel for First Aid, storage, disposal and other precautionary statements and uses.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

SANITIZING - FOOD PREPARATION AREAS

For use on sinks, drain and cutting boards, counter tops, forks, knives, dishes, utensils, and salad preparation surfaces in kitchens, restaurants, other eating establishments, dairies and food processing plants.

CLEANING STEP: 1. Flush surfaces with water to remove heavy soil. 2. Clean surfaces by applying a 1% (one pouch/ 8 gal) - 2% (one pouch/ 4 gal) solution of PRO-SAN®, prepared by stirring the powder to dissolve in water, applied by brush, foam, wiping, or low-pressure spray. 3. Rinse with potable water.

SANITIZING STEP: 1. Sanitize by applying a 1% PRO-SAN® (one pouch/ 8 gal) solution prepared by stirring to dissolve sanitizer powder in water. 2. Apply sanitizer by immersion, flooding, or spraying. Allow to completely wet surfaces for one minute or for a contact time specified by local and state sanitary code. 3. Drain and allow sanitized surfaces to air dry.

Manufactured for:  **MICROCIDE®, INC.,**
Detroit, MI 48201

FRUIT AND VEGETABLE WASHING

1. Prepare a cleaning solution by adding PRO-SAN® powder to potable (drinking) water at room temperature by stirring to dissolve, preparing a 1% (one pouch / 8 gal) or 2% (one pouch / 4 gal) of cleaning solution. Select the concentration depending on the amount of soil present on the fruit or vegetable.

2. Immerse fruits and vegetables in cleaning solution and wash by gentle hand scrubbing with a brush, mesh pad or by mechanical agitation in a tumble washer. Repeat washing with fresh cleaning solution if needed.

3. Thoroughly rinse cleaned fruits and vegetables with potable water to remove soil, and cleaner residue. Drain excess liquid.

U.S. Patents: 5,143,720 & 5,280,042

EPA Registration No. 71094

EPA Est. No. 034637-OH-001

NET WT. 0.67 LB (0.3 Kg)

BACK PANEL OF PRO-SAN LABEL

FIRST AID

IF ON 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 a physician for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists.

IF SWALLOWED: Have person sip a glass of water if able to swallow. Do not give anything by mouth to an unconscious person. Call Poison Control Center or a physician. Do not induce vomiting unless advised by Poison Control Center or a physician.

IF INHALED: Move a person to fresh air. If person is not breathing, Call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible; Call a Poison Control Center or doctor for further treatment advice.

Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment.

In case of emergency call toll free Emergency Response Telephone Number: 1-888-342-6279

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

CIRCULATION CLEANING & SANITIZING OF EQUIPMENT

(Soft Ice Cream, Juice, and Vending Machines)

CLEANING STEP: 1. Flush system with clean, warm water. 2. Disassemble parts needing manual cleaning. 3. Clean using a 1% (one pouch / 8 gal) - 2% (one pouch / 4 gal) solution of PRO-SAN® prepared by stirring the powder in water. 4. Assemble circulating parts. 5. Fill system to capacity. 6. Circulate for 5-10 minutes. 7. Drain.

SANITIZING STEP: 1. Sanitize with a fresh solution of 1% PRO-SAN® prepared by stirring contents of one pouch to dissolve in 8 gallons of water. 2. Fill equipment to capacity and re-circulate for 2-5 minutes. 3. Drain and allow to air dry. *(Used PRO-SAN® solution may be reused for cleaning equipment but not for sanitizing. Test sanitizer solution to maintain a pH of 2.2 - 2.8. Discard sanitizer if it becomes visibly dirty or its pH increases.)*

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive causes irreversible eye damage. Do not get in the eyes. Wear protective eye wear (goggles, face shield, or safety glasses). Harmful if swallowed or inhaled. Avoid breathing dust. Avoid contact with skin, eyes and clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Note: An acidic product. Do not mix with bleach or chlorinated products as toxic or irritating chlorine fumes may be released.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a cool, dry area. Keep this product in tightly closed container.

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

CONTAINER DISPOSAL: Dispose outer product shipping container in trash. Triple rinse plastic pouch. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

SANITIZING-FOOD PREPARATION AREAS: For use on sinks, drain and cutting boards, counter tops, forks, knives, dishes, utensils, and salad preparation surfaces in kitchens, restaurants, other eating establishments, dairies and food processing plants.

CLEANING STEP: 1. Flush surfaces with water to remove heavy soil. 2. Clean surfaces by applying a 1% (one pouch / 8 gal) - 2% (one pouch / 4 gal) solution of PRO-SAN prepared by stirring to dissolve the powder in water or using similar acid cleaner, applied by brush, foam, wiping, or low-pressure spray. 3. Rinse with potable water.

SANITIZING STEP: 1. Sanitize by applying a 1% PRO-SAN solution prepared by stirring to dissolve the contents of one pouch in 8 gallons of water. 2. Apply sanitizer by immersion, flooding, or spraying. Allow to completely wet surfaces for one minute or for a contact time specified by local and state sanitary code. 3. Drain and allow sanitized surfaces to air dry.

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U.S. Patents: 5,143,720 & 5,280,042

EPA Reg. No. 71094-1; EPA Est. No. 034637-OH-001

Manufactured for:  MICROCID® INC., Detroit, MI 48201

12 X 0.67 LB (0.3 Kg) Pouches

NET WT: 8.02 LBS (3.64 Kg)

NOTIFICATION
Date Reviewed: 12-3-07
Reviewed By: H. G. Smith

CIRCULATION CLEANING & SANITIZING OF EQUIPMENT (Soft Ice Cream, Juice, and Vending Machines)

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