

70369-1

04/13/2006

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

April 13, 2006

Georgia Anastasiou
Agent for ChemLink Laboratories, LLC
c/o Lewis & Harrison
122 C St., NW Suite 740
Washington, DC 20001

Subject: Microstat 2
EPA Registration No. 70369-1
Application Date: April 3, 2006
Receipt Date: April 5, 2006

Dear Ms. Anastasiou:

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

Proposed Notification

- addition of inserts reiterating directions for use

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) 308-6345.

Sincerely,

Wanda Y. Henson
Product Reviewer (32)
Regulatory Management Branch II
Antimicrobials Division (7510C)

CONCURRENCES

YMBOL	7510C	7510C						
JRNAME	F. B. G.	W. Henson						
ATE	4/13/06	4/13/06						

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LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001

telephone 202.393.3903
fax 202.393.3906

HAND DELIVERED

April 3, 2006

US EPA
Office of Pesticide Programs (7504C)
Document Processing Desk (NOTIF)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 Bell Street
Arlington VA 22202

**ATTENTION: Emily Mitchell
Product Manager, Team 32**

**SUBJECT: ChemLink Laboratories, LLC
Microstat 2 (EPA Reg. No. 70369-1)
Application for Pesticide Notification**

Dear Ms. Mitchell:

On behalf of ChemLink Laboratories, L.L.C., we are submitting a notification for the product, Microstat 2 (EPA Reg. No. 70369-1). The purpose of this submission is to notify the Agency of two inserts that will be included in the final packaging.

Insert 1: These are stickers that remind the customer to change the solution every 7 days. **Please note that the direction to change the solution every 7 days is approved language that can also be found on the main label.**

Insert 2: This is a reminder for the customer to remove residue left from other surface cleaners before using Microstat 2.

Enclosed please find the following documents to support this amendment:

- 1) Application for Pesticide Notification (OPP ID No. 265394);
- 2) One (1) copy of each insert; and,
- 3) One (1) copy of the approved product labeling.

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Insofar as Lewis & Harrison is the agent for ChemLink, please direct any questions or correspondence directly to us. If you have any questions or need any additional information, please call me at 202-393-3903 ext. 19 or e-mail me at georgia@lewisharrison.com.

Thank you very much for your assistance with this submission.

Sincerely,



Georgia Anastasiou
Agent for,
ChemLink Laboratories

Enclosures

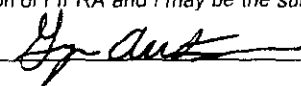
cc: Micquie Howard (ChemLink)
Grady Schleier (Chemlink)

 EPA	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other: Notification	OPP Identifier Number 265394
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Application for Pesticide - Section I

1. Company/Product Number 70369-1	2. EPA Product Manager Emily Mitchell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Microstat 2	PM# Team 32	
5. Name and Address of Applicant (Include ZIP Code) ChemLink Laboratories, LLC 1590 North Roberts Road NW, Suite 111 Kennesaw, GA 30144 <u>PLEASE DIRECT ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <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 _____

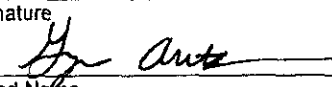
Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) <p style="text-align: center;">PLEASE REFERENCE COVER LETTER FOR DETAILS</p> <p style="text-align: center;">Notification of ADDITIONAL Marketing Language and Individual Foil Package Label in Accordance With PR Notice 98-10</p> <p><i>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 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be the subject to enforcement action and penalties under sections 12 and 14 of FIFRA.</i></p> Signature: <u></u> Date: <u>4/3/06</u>	

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 <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 type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name: Georgia Anastasiou, Lewis and Harrison, LLC 122 C St., NW Suite 740 Washington, DC 20001	Title: Agent for ChemLink Laboratories, LLC	Telephone No. (include Area Code): (202) 393-3903 ext. 19
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 <u></u>		
3. Title: Agent for ChemLink Laboratories, LLC		
4. Typed Name Georgia Anastasiou, Lewis & Harrison LLC		
		5. Date April 3, 2006

MICROSTAT 2™ (LABEL COPY 16 UNIT BOX)

MICROSTAT 2™
Hospital Surface Disinfectant

Tuberculocidal**, Bactericidal, Virucidal*, Fungicidal

Active Ingredients	
Sodium Bromide ¹	9.70%
*** Sodium Dichloroisocyanurate Dihydrate ²	24.75%
Other Ingredients	65.55%
	Total
	100.00%

¹Tablet A contains 19.4% sodium bromide as the sole active ingredient
²Tablet B contains 49.5% sodium dichloroisocyanurate dihydrate as the sole active ingredient

* on hard, nonporous, inanimate surfaces
** in five minutes @ room temperature (20°C)
***) 3.75% total available chlorine (27.5% in Tablet B)

Contents: 16 sets (Tablet A/ Tablet B) in foil packets

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
If in eyes:	<ul style="list-style-type: none"> • 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 eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none"> • 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 swallowed:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have a person sip a glass of water if able to swallow. • 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.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

Precautionary Statements

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Wear rubber gloves and safety glasses or face shield when making up solution. Avoid direct contact with eyes, skin or clothing. If direct contact with eyes occurs, may cause eye injury. Harmful if absorbed through the skin. Wash thoroughly with soap and water after handling.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. MICROSTAT 2 is designed to provide effective disinfection of hard, nonporous, inanimate environmental surfaces in dental, medical, hospital and veterinary facilities. This product has demonstrated the ability to be an effective bactericide in water up to 400 PPM hardness (as CaCO₃) in the presence of organic soil (5% blood serum).

TO PREPARE SOLUTION FOR USE: Fill the one quart spray bottle to the mark with room temperature (22°C/72°F) water. Open the foil packet for *Tablet A* and drop tablet into the spray bottle. Carefully open the foil packet for *Tablet B* being certain not to touch the tablet with your fingers and drop the tablet into the sprayer bottle. If fingers come in contact with *Tablet B* immediately wash hands with plenty of soap and water. When effervescing stops and tablets are completely dissolved (about 3 minutes), the disinfectant solution is ready for use and is effective against *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, *Bordetella bronchiseptica*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*, *Candida albicans*, *Adenovirus Type IV*, *Canine parvovirus*, *Pseudorabies*, *Canine rubella*, *Canine distemper*, *Feline picornavirus*, *Feline leukemia*, *Feline panleukopenia*, *Porcine parvovirus*, *Infectious bovine rhinotracheitis*, *Infectious bronchitis (Avian IBV)*, *Mycobacterium tuberculosis var. bovis***, *Trichophyton mentagrophytes (Pathogenic fungi)*, *Escherichia coli*, *Herpes Simplex Virus Types 1 and 2**, *Polio Virus Type 1 and 2**, *Coxsackie Virus**, *Influenza A (Hong Kong)**, and *Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus)**. Once solution has been prepared, the product has an effective shelf-life for up to seven (7) days and may be used as a stock solution for up to seven days. The seven-day stock solution should be mixed in an opaque bottle and stored in a dark cabinet away from direct lighting between uses.

FOR DISINFECTION: To disinfect floors, walls, tables, sinks, bathrooms, shower areas, dressing rooms, locker rooms, and other hard, nonporous, inanimate environmental surfaces, prepare MICROSTAT 2 solution as directed above. Remove excess organic debris and thoroughly clean surface prior to application of MICROSTAT 2. Thoroughly spray surfaces to be disinfected, re-spraying as necessary, and allow surfaces to remain wet for 5 minutes. When contact period has concluded, rinse surfaces with potable water or allow surfaces to air dry. *Although MICROSTAT 2 has been shown to destroy HIV-1 (Aids Virus) in 60 seconds contact time, this time is not sufficient for the organisms. It is recommended that a five-minute contact time be used against all organisms. Label.*

(Directions for Use continued on right panel)

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON PRECLEANED ENVIRONMENTAL SURFACES/ OBJECTS SOILED WITH BLOOD/BODY FLUIDS: In health care settings or other settings where there is an expected likelihood of soiling inanimate surfaces/ objects with blood or body fluids, and where the surfaces/ objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (AIDS Virus) the following special procedures must be used: **PERSONAL PROTECTION:** When handling items soiled with blood or other body fluids wear protective equipment, including disposable latex or rubber gloves, gowns, masks, and eye coverings. **CLEANING PROCEDURE:** Blood or other body fluids must be thoroughly cleaned from the soiled surfaces and objects before MICROSTAT 2 can be applied. **CONTACT TIME:** To kill HIV-1 (AIDS Virus), a contact time of 5 minutes at room temperature. **DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

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 blood stream 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 of high level disinfection.

NON-POROUS IMPRESSION MATERIALS: For the disinfection of non-porous dental impression materials such as vinyl poly siloxane, polysulfide, and silicon, upon removal of impression from mouth, remove gross debris from impression by rinsing thoroughly with running water. Using a suitable container, immerse impression for 5 minutes in MicroStat 2 solution (1 tablet A and 1 tablet B dissolved in one quart of water). Impression must be completely immersed in solution. After 5 minutes, remove impression and rinse thoroughly with running water. Change solution daily or when visibly soiled.

INSTRUMENT SOAK: For soaking of instruments prior to cleaning and terminal sterilization, place instruments in suitable container filled with MicroStat 2 solution (1 tablet A and 1 tablet B dissolved in one quart of water). Instruments must be completely immersed in solution for 5 minutes. Upon removal, rinse with running water and proceed with final cleaning and terminal sterilization procedures. Change solution daily or when visibly soiled.

FOR USE WITH GENERAL PURPOSE ULTRASONIC CLEANING EQUIPMENT: For ultrasonic cleaning of items prior to terminal sterilization, place items to be cleaned in ultrasonic bath containing MicroStat 2 solution (1 tablet A and 1 tablet B dissolved in one quart of water), ensuring that items are fully immersed in solution. Run ultrasonic unit for 5 minutes. Remove items and rinse thoroughly under running water and proceed with terminal sterilization procedures. Change solution daily or when visibly soiled.

STORAGE AND DISPOSAL: Store in a cool, dry, well ventilated area. Do not store at temperatures above 40°C/104°F.

FPA Reg. No. 70369-1 EPA Est. No. 69781-AIN-01
Net Weight: 97.6 grams (3.44 ounces)
Chemlink Laboratories LLC, Kennesaw, GA 30144
For exclusive distribution by
Septodont, Inc., New Castle, Delaware 19720
FOR TECHNICAL ASSISTANCE, CALL (800) 872-8305

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PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of *this product may be disposed of on-site, in a toilet, or service sink served by a sanitary sewer or an approved waste disposal facility for pesticides.*

CONTAINER DISPOSAL: Do not reuse empty packet. Wrap packet and place in normal trash.

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INSERT 1

Change
your
Microstat 2
on

MONDAY

Change
your
Microstat 2
on

TUESDAY

Change
your
Microstat 2
on

WEDNESDAY

Change
your
Microstat 2
on

THURSDAY

Change
your
Microstat 2
on

FRIDAY

REMEMBER:

**Change
Microstat™2
solution
every 7 days.**

INSERT 2



MicroStat 2
monitor Broad Surface Disinfection

MicroStat 2 is a portable, battery-powered, microprocessor-controlled disinfection monitor. It is designed to monitor the effectiveness of disinfection procedures in a wide range of environments, including hospitals, laboratories, and other facilities where high standards of hygiene are required. The device provides real-time feedback on disinfection levels, ensuring that surfaces are properly disinfected and reducing the risk of infection.