

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



United States
Environmental Protection
Agency

Office of Pesticide Programs

MAY 19 2010

FILE COPY

Christina M. Swick
Agent for Chemlink Laboratories LLC
Lewis & Harrison
122 C Street, N.W.
Suite 740
Washington, DC 20001

Subject: Microstat 2
EPA Reg. No. 70369-1
Application Dated: April 21, 2010
Receipt Date: April 21, 2010

Dear Ms. Swick:

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9 is acceptable.

Proposed Notification:

- Revise Container Disposal section per PR Notice 2007-4 by adding statement "Offer for recycling, if available, or..."

Comments:

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

This application for notification to revise the container disposal section, as referenced above, is acceptable and has been made a part of the file for this product.

Should you have any questions concerning this letter, please contact me at Henson.Wanda@epa.gov or call (703) 308-6345.

Sincerely,

Wanda Henson
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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Please read instructions on reverse before completing form. Form Approved MB No. 2070-0060, Approval expires 05-31-98



EPA

United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other NOTIFICATION

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number 70369-1	2. EPA Product Manager Wanda Henson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Microstat 2	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) ChemLink Laboratories, LLC 1590 North Roberts Road NW, Suite 111 Kennesaw, GA 30144 PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW <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 LABEL CHANGE PER PR NOTICE 2007-4

This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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.

Signature: Christina M. Swick

Date: 4/21/10

THIS SUBMISSION IS NOT SUBJECT TO PRIA FEES

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	
*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"/> 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 Christina M. Swick, Lewis & Harrison 122 C Street, NW, Suite 740, Washington DC 20001	Title Agent	Telephone No. (Include Area Code) 202-393-3903 x16
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>Christina M. Swick</u>	3. Title Agent	
4. Typed Name Christina M. Swick, Lewis & Harrison, LLC	5. Date April 21, 2010	

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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

April 21, 2010

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HAND DELIVERED

Antimicrobials Division (Mail Code 7504P)
Office of Pesticide Programs
Document Processing Desk [NOTIFY]
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN: Wanda Henson
Product Manager, Team 32

SUBJECT: Chemlink Laboratories LLC
Microstat 2 (EPA Reg. No. 70369-1)
Notification of Label Changes per PR Notice 2007-4

Dear Ms. Henson:

On behalf of Chemlink Laboratories LLC, we are notifying the Agency of changes to the *Microstat 2* label. The changes are in accordance with PR Notice 2007-4. All of the language has been added verbatim from the aforementioned PR Notice. No other changes have been made to the label.

Please note that *Microstat 2* tablets are packaged in foil blister packs. As a result, the container label is exempt from the majority of the language required by PR Notice 2007-4.

Please find enclosed the following documents to support this notification:

- 1) Pesticide Application Form;
- 2) One (1) copy of the proposed product label with the changes marked; and,
- 3) Three (3) copies of the proposed product label.

If you have any questions or comments, please contact me at 202-393-3903 ext. 16 or cswick@lewisharrison.com.

Sincerely,

Christina M. Swick

Christina M. Swick
Agent for Chemlink Laboratories LLC

MICROSTAT 2™

(LABEL COPY 16 UNIT BOX) [(LABEL COPY 12 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)

***13.75% total available chlorine (27.5% in Tablet B)

****7.54% as total available bromine (15.07% in Tablet A)

Contents: 16 sets (Tablet A/Tablet B) in foil packets
[12 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.	

EPA Reg. No. 70369-1

EPA Est. No. 69781-MN-01

Net Weight: 97.6 grams (3.44 ounces)

[Net Contents Per Box: 0.85 Ounces (3g) Each

Twelve (12) A Tablets, Twelve (12) B Tablets]

Chemlink Laboratories LLC, Kennesaw, GA 30144
FOR TECHNICAL ASSISTANCE, CALL (800) 872-8305

NOTIFICATION

Date Reviewed: 5/19/2010
Reviewed By: [Signature]

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:

[Follow enclosed directions for use]

[See package insert]

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* [or Press *Tablet A* through the foil of the blister pack] and drop tablet into the spray bottle. Carefully open the foil packet for *Tablet B* [or Press *Tablet B* carefully through the foil of the blister pack] 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 enterica*, *Methicillin-Resistant Staphylococcus aureus* [MRSA] (ATCC 33592), *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 A2* [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 DISINFECTING: 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 other organisms. It is recommended that a five-minute contact time be used against all organisms claimed.*

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 autoclave/ 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 pre-clean 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.

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FOR USE IN BEAUTY SALONS, SPA SALONS, BARBERSHOPS & HAIR STYLING FACILITIES

Microstat 2 is recommended for use on brushes, combs, rollers, manicure and other tools used in, beauty salons, spa salons barbershops, and hair styling facilities. Fill the standard disinfectant jar with 32 ounces of water. Open the foil packet (marked Tablet A) and drop into the jar. Carefully open (marked Tablet B) being certain not to touch the tablet with your fingers and drop the tablet into the jar. If fingers come in contact with *Tablet B*, immediately wash hands with plenty of soap and water. The tablets should dissolve in approximately 3 minutes, and the disinfectant solution is ready to use.

For Disinfection: Thoroughly clean & rinse instruments before immersion into disinfection solution. Immerse instruments completely for (5) minutes at room temperature (22°C/72°F). After immersion, remove instruments and rinse thoroughly. Change solution daily or when visibly soiled.

Once the solution has been prepared, it has a shelf life for up to seven (7) days and may be used as a stock solution for up to seven (7) 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 CLEANING AND DISINFECTION OF FOOT SPA BASINS IN SALONS

Consumer Precautions – Protecting The Client

1. Check the condition of the client's feet and legs. If open sores or skin wounds are present (including insect bites, scratches, scabbed-over wounds, or any condition that weakens the skin barrier), explain to the client why they should not use the foot bath.
2. Complete pedicure or wax after the foot bath soak. Any procedure that risks damage to a client's skin should not be done before soaking feet in the foot spa basin.

After Each Client

These disinfection procedures can take place any time after the client's feet are out of the footbath, while feet are massaged, toes are manicured and painted, or during other opportunities after the client is finished with the footbath.

For All Foot Spa Baths:

1. **Drain** the water from the foot spa basin or bowl and remove any visible debris.
2. **Prepare** a one-quart bottle of MICROSTAT 2 use solution as directed in the "Prepare Solution For Use" section.
3. After cleaning **spray** all surfaces of the foot spa basin and allow to stand for at least 5 minutes.
4. After five minutes, drain and rinse with clean water.

For Disinfecting Whirlpool Foot Spas, Air-Jet Basins, "Pipe-Less" Foot Spas, And Other Circulating Spas:

1. **Fill** the basin with 5 gallons of clean water.
2. **Make up a liquid disinfectant solution in the basin water** using ten sets of Tablet A and Tablet B. Open foil packets of Tablet A and drop [Press Tablet A through the foil of the blister pack] into the basin. Carefully open packets of Tablet B [Press Tablet B carefully through the foil of the blister pack], being certain not to touch the tablet with your fingers, and drop into the basin. If fingers come in contact with Tablet B, immediately wash hands with plenty of soap and water. The tablets should dissolve in approximately 3 minutes.
3. Turn the foot spa unit **on** and **circulate** the disinfectant for at least 5 minutes.
4. **Drain** the basin after the disinfection period is complete and rinse with clean water.

[Nightly] [End Of Day] [Daily] Disinfection

For Whirlpool Foot Spas, Air-Jet Basins, "Pipe-Less" Foot Spas, And Other Circulating Spas:

1. **Remove** the filter screen, inlet jets, and all other removable parts from the basin and clean out any debris trapped behind or in them.
2. **Prepare** a one-quart bottle of MICROSTAT 2 use solution as directed in the "Prepare Solution For Use" section.
3. **Spray** all surfaces of the removable parts with the MICROSTAT 2 use solution. Using a clean brush, **scrub** these parts with the MICROSTAT 2 use solution (following cleaning directions).
4. **Fill** the basin with 5 gallons of clean water
5. **Make up a liquid disinfectant solution in the basin water** using ten sets of Tablet A and Tablet B. Open foil packets of Tablet A and drop [Press Tablet A through the foil of the blister pack] into the basin. Carefully open packets of Tablet B [Press Tablet B carefully through the foil of the blister pack], being certain not to touch the tablet with your fingers, and drop into the basin. If fingers come in contact with Tablet B, immediately wash hands with plenty of soap and water. The tablets should dissolve in approximately 3 minutes.
6. Turn the foot spa unit **on** and **circulate** the system for at least 5 minutes. The whirlpool mechanism of the tub must be operating for the entire disinfection period so the piping and internal components that contain hidden bacteria are disinfected.
7. **Drain** the basin after the disinfection period is complete.
8. Rinse basin then air dry

For Simple Basins (No Circulation):

1. **Drain** the basin and remove any visible debris.
2. **Scrub** the bowl with a clean brush and soap or disinfectant (following cleaning directions). Rinse and drain.
3. **Prepare** a one-quart bottle of MICROSTAT 2 use solution as directed in the "Prepare Solution For Use" section.
4. **Spray** all surfaces of the foot spa basin thoroughly with the MICROSTAT 2 use solution and **scrub** the basin with a clean brush (following cleaning directions). Surfaces must remain wet with the MICROSTAT 2 use solution for at least 5 minutes.
5. **Drain** the basin, rinse with clean water, and let air dry.

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

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. Offer for recycling, if available, or wrap packet and place in normal trash.

[Optional Marketing Language]

- Disinfects hard nonporous surfaces
- Disinfects nonporous dental impression materials
- For the soaking of instruments prior to cleaning and terminal sterilization
- For ultrasonic cleaning of items prior to terminal sterilization
- Disinfectant Tablets
- 2 tablets make 1 quart (.95 L)
- 16 sets (Tablet A & Tablet B) makes 16 quarts (15L)
- For use in beauty salons, spa salons, barbershops, hair styling facilities & hospitals
- Microstat 2 is recommended for use on brushes, combs, rollers, manicure & other tools used in spa salons, beauty salons, barbershops, and hair styling facilities
- Microstat 2: The solution is effective against Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella enterica, Methicillin-Resistant Staphylococcus aureus [MRSA] (ATCC 33592), 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 A₂ [Hong Kong]*, and Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus]*