

70369-1

08/13/2008

1/4

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

FILE COPY



Office of Pesticide Programs

August 13, 2008

Wendy McCombie
Lewis & Harrison
122 C Street, NW
Suite 740
Washington, DC 20001

Subject: **ChemLink Laboratories, LLC**
Microstat 2
EPA Reg. No. 70369-1
Application Date: April 24, 2008
Receipt Date: May 2, 2008

Dear Ms. McCombie:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is accepted with conditions/comments.

The submitted data support the proposed label claims that the product, Microstat 2, is an effective disinfectant on hard, non-porous surfaces against the following microorganism in the presence of 5% fecal bovine serum for a contact time of 5 minutes with 1 tablet of A and 1 tablet of B diluted in one quart of 400 ppm hard water:

Methicillin Resistant *Staphylococcus aureus* (ATCC# 33592)

Conditions

1. Provide more detailed information on the use sites (i.e., surfaces and materials).
2. Change the designation of the organism formerly called *Salmonella choleraesuis* to *Salmonella enterica*. The American Type Culture Collection, which has jurisdiction over nomenclature of microorganisms made the change in 2006, and the Agency has adopted the new name to be more representative of a human, rather than an animal pathogen.


3. The ATCC designation numbers are required in the following locations:
- on the data matrix;
 - on the master label (as optional text) with the listing of the organisms claimed; or
 - As the final page of the master label (as optional text)
4. Bold the following sub-headings
- a. **For All Foot Spa Baths**
 - b. **For Disinfecting Whirlpool Foot Spas, Air-Jet Basins, Pipe-Less Foot Spas And Other Circulating Spas**

General Comments

A stamped copy of the labeling is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please call Wanda Henson at (703) 308-6345.

Sincerely,



Emily H. Mitchell

Product Manager - Team 32

Regulatory Management Branch II

Antimicrobials Division (7510C)

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 (24.1g) Each

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

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

AUG 13 2008

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]

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 1/2 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 enteritidis*, *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 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 other organisms. It is recommended that a five-minute contact time be used against all organisms claimed.*

EPA Reg. No. 70369-1/ Page 1 of 2

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 a. 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.

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide

70369-1

3/4

Revised February 7, 2008

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 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.

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. 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 choleraesius, 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]*

ACCEPTED
with COMMENTS
EPA Letter Dated:

AUG 13 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 70369-1

1/4