

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

December 15, 2003

Georgia Anastasiou
Lewis & Harrison
122 C Street, NW
Suite 740
Washington, DC 20001

Subject: Chemlink Laboratories, LLC
Microstat 2
EPA Registration No. 70369-1
Application Date: September 23, 2003
Receipt Date: September 24, 2003

Dear Ms. Anastasiou:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

Conditions

- 1. Revise the Ingredient statement as follows:

Active Ingredients:

Sodium Bromide ¹	9.70%
Sodium Dichloroisocyanurate Dihydrate ²	24.75%
Other Ingredients	66.55%
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.

- 2. Separate the signal word **CAUTION** from **KEEP OUT OF REACH OF CHILDREN**.

CONCURRENCES

SYMBOL	7510C						
SURNAME	Mitchell						
DATE	12-15-03						

74

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit a 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 contact Wanda Mitchell at (703) 308-6345.

Sincerely,

*Robert S. Brennis
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)*

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%
Inert 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)

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 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 with MICROSTAT 2.*

(Directions for Use continued on right panel)

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

EPA Reg. No. 70369-1
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

DEC 15 2003

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 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.

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

3/14

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.

ACCEPTED
with COMMENTS
EPA Letter Dated:

DEC 15 2003

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

043

04300

1/1/1