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U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (H7505C) 401 "M" St., S.W. Washington, D.C. 20460

NOTICE OF PESTICIDE:

x Registration
Reregistration

(under FIFRA, as amended)

EPA Reg. Number: Date of Issuance:

JUN 1 1 1997

70369-1

Term of Issuance:

Conditional

Name of Pesticide Product:

Microstat 2[™]

Name and Address of Registrant (include ZIP Code):

Southland, Ltd.

1590 North Roberts Road, NW, Suite 111

Kennesaw, Georgia 30144

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a posticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
 - 2. Make the following label changes:
 - a. Revise the EPA Registration Number to read, "EPA Reg. No. 70369-1".
 - b. Under the directions to prepare solution for use on the left panel, the use directions should be expanded to specify that the 7 day stock solution should be mixed in a dark bottle and stored in a dark cabinet away from direct lighting between uses.
 - c. On the left panel, revise "Influenza Viruses Types 1 and 2" to read "Influenza A2 (hong kong)". The accepted virucidal data supports only the strain "influenza A2 (hong kong)".

Signature of Approving Official:

Date:

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EPA Form 8570-6

To show consistency for all of the proposed virucidal claims, the label directions should be expanded to include and add an asterick by each specific virus claim on the label.

- d. On the left panel, revise "Trichophytin" to read "Trichophyton". After mentagrophytes, add "(Pathogenic fungi)".
- e. On the center panel, revise "on inanimate surfaces" to read "on hard, nonporous, inanimate surfaces".
- f. Under the direction for disinfection, the types of surfaces intended for treatment should be expanded to include hard surfaces found in bathrooms, shower areas, dressing rooms and locker rooms. These surfaces are areas where <u>Trichophyton mentagrophytes</u> are normally found.
- 3. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Robert S. Brennis

Acting Product Manager (32)
Regulatory Management Branch II

Antimicorbial Division (7504C)

BEST AVAILABLE COPY

MICROSTAT 2[™] (LABEL COPY 16 UNIT BOX)

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 Choleracsius, Mycobacterium Tuberculosis var.bovis**, Trichophytin Mentagrophytes, Escherichia Coli, Herpes Simplex Virus Types 1 and 2, Polio Virus Type 1 and 2*, Coxsackie Virus*, Influenza Virus Types 1 and 2, 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.

FOR DISINFECTION: To disinfect floors, walls, tables, sinks, 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 10 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 ten-minute contact time be used against all organisms claimed. (Directions for Use continued on right panel)

MICROSTAT 2TM
Hospital Surface Disinfectant

Tuberculocidal **, Bactericidal, Virucidal*, Fungicidal

Active Ingredients:

Sodium Bromide ^r	9.70%
***Sodium Dichloroisocyanurate Dihydrate2	24.75%
Inert Ingredients	<u>65,55%</u>
Total	100.00%

Tablet A contains 19.4% sodium bromide as the sole active ingredient,

²Tablet 13 contains 49.5% sodium dichloroisocyanurate dihydrate as the sole active ingredient.

- * on inanimate surfaces
- ** in ten minutes @ room temperature (20°C)

 Contents: 16 sets (Tablet A/Tablet B) in foil packets
- ***13.75% total available chlorine (27.5% in Tablet B)

KEEP OUT OF REACH OF CHILDREN CAUTION

Precautionary Statements

HAZARDS TO HUMANS AND DOSMETIC 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.

STATEMENT OF PRACTICAL TREATMENT:

If in eyes; flush with plenty of water for fifteen minutes.

Seek medical attention if irritation persists. If on skin; wash thoroughly with plenty of soap and water. Seek medical attention if irritation persists. If swallowed; call a physician or Poison Control Center. Drink one or two glasses of water and induce vomiting. If person is unconscious, do not give anything by mouth and do not induce vomiting.

EPA Reg. No. 70369- EPA Est. No. 69781-MN-01

Southland, Ltd., Kennesaw, GA 30144

For exclusive distribution by Septodont, Inc., New Castle,

Delaware 19720

FOR TECHNICAL ASSISTANCE, CALL (800) 872-8305

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 10 minutes at room temperature. DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclayed 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.

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.

with COMMENTS in EPA Letter Dated:

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Revised 4/29/97

Under the rederal Inserticide, Pungleide, and Redenticide Act as emonded, for the posticide registered under EPA Reg. No.

0369-1