

72977-3

3-3-2003

1/7



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460-0001

EPA Reg. Number:

72977-3

Date of Issuance:

March 3, 2003

NOTICE OF PESTICIDE:

Registration
 Reregistration

(Under FIFRA, as amended)

Terms of Issuance:

Conditional

Name of Pesticide Product:

AXEN® 30

Name and Address of Registrant (include ZIP Code):

**Innovative Medical Service
1725 Gillespie Way
El Cajon, California 92020**

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 pesticide 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 section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA section 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 labeling changes listed below before you release the product for shipment:
 - a. Revise the EPA Registration Number to read "EPA Registration Number 72977-3"

Signature of Approving Official:

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

Date:

March 3, 2003

- b. On page 2, the chart which listed the kill time under the heading **General Information** for the bacteria "*Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis* and *Listeria monocytogenes* must be changed from 30 second to **Two Minutes** in the chart and, wherever it appears on the label."
- c. The kill time for Herpes Simplex Type 1 VR-733 F(1) Strain must be changed from one minute to **Ten Minutes** in the chart and, wherever it appears on the label.
- d. On the 4th page of the label, delete the statements "eliminates" or "Kills 99.99999, etc . . ." Only the following statements under the headings on page 4 of the label are acceptable:

Additional Language for Front Panel

- Kill common household germs
- Kill common household germs, including Salmonella, Staphylococcus, Listeria and E. coli.
- Kills Bacteria, Fungus and Virus*

Alternate Language for the Back Panel

- None of the alternate language for the back panel is acceptable and therefore must be deleted from the label.
- e. Delete the word "***Eliminates***" wherever it appears on the label and replaces it with the word "to kill or to control."
- f. Delete the ingredient "Ionic Sliver" from the product name or add the ingredient "Citric Acid" to the product name.
- g. The "Keep Out of Reach of Children" statement must be placed below the ingredient statement, along with the signal word "**Caution.**"
- h. Since no residual data was submitted to support the claim "*Do not clean treated surfaces after application if 24 hour protections are expected to be maintained,*" you must delete the claim wherever it appears on the label.
- i. With respect to the statement concerning Athlete's foot fungus, delete the statement, "and any other hard, non-porous surfaces."

- j. Since this product will be used in hospital and other health facilities, the following statement must be added to the label:

“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 human body, either into or in contact with the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not enter ordinarily penetrates the blood barrier or otherwise enter normal sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.”

Refer to PR Notice 94-4 for detailed information.

- h. Delete the statement, “and other areas requiring control of microbial contamination” from the direction for use section. All intended cites must be specified on the label.
- i. In the second paragraph on page 2, delete the word “such as” and other areas of the label where it appears.

Refer to the EPA letter dated January 28, 2003 for detailed information and/or unacceptable label statements.

- 3. Submit three (3) copies of the revised final printed label bearing the revisions prior to releasing this product for sale.

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

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

Sincerely,



Adam Heyward
 Product Manager (34)
 Regulatory Management Branch II
 Antimicrobials Division (7510C)

Enclosure:

4/7

Stabilized Ionic Silver
Axen® 30
Disinfectant, Fungicide & Virucide*

Disinfects and Deodorizes
Restaurants • Hospitals • Schools • Homes • Offices

ACCEPTED
with COMMENTS
- EPA Letter Dated:

MAR - 3 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 72977-3

KEEP OUT OF REACH OF
CHILDREN

<u>Active Ingredient</u>	
Silver†	0.003%
Citric Acid	4.840%
<u>Other Ingredients</u>	95.157%
Total	100.000%

† Electrolytically generated Silver ions

Manufactured by ETI H2O
A Division of Innovative Medical
Services
1725 Gillespie Way
El Cajon, CA 92020

EPA REG. No. 72977-
EPA EST. No. 72977-CA-001

Net Vol. 32 oz.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to eliminate bacteria, fungus and viruses*, **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** should be used on non-porous environmental hard surfaces in homes, hospitals, nursing homes, medical and dental clinics, laboratories, ambulance and patient transfer vehicles, funeral homes, hotels, restaurants, schools, day care facilities, offices, veterinary clinics, animal shelters, kennels, exercise facilities, beauty and barber shops, subways, trains, airplanes, ships, busses and other public transportation vehicles, locker rooms, kitchens, restrooms and other areas requiring control of microbial contamination.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray has been formulated to disinfect hard, non-porous environmental surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) and objects such as walls, floors, counters, sinks, toilets, cabinets, tubs, showers, doorknobs, lights switch covers, telephones, appliances, stove tops, bed frames, wheelchairs, over-bed tables, examination tables and waste containers, tables, and chairs.

FAST, EASY, EFFECTIVE General Information

* **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** demonstrated effective elimination of the following organisms under AOAC protocols:

Organism	Kill Time
<i>Pseudomonas aeruginosa</i> ¹	30 seconds
<i>Staphylococcus aureus</i> ¹	30 seconds
<i>Salmonella choleraesuis</i> ¹	30 seconds
<i>Listeria monocytogenes</i> ¹	30 seconds
Vancomycin resistant <i>Enterococcus faecium</i> ¹	2 minutes
Methicillin resistant <i>Staphylococcus aureus</i> ¹	2 minutes
<i>Escherichia coli</i> 0157:H7 ¹	2 minutes
<i>Trichophyton mentagrophytes</i> (Athlete's Foot Fungus)	10 minutes
HIV type 1- Strain HTLV IIIB ¹	30 seconds
Herpes Simplex Type 1 VR-733 F(1) Strain ²	1 minute
Influenza A VR-544, Hong Kong strain ²	10 minutes
Rhinovirus R37 VR-1147, Strain 151-1 ²	10 minutes
Polio Type 2, VR-1002, Lansing Strain ²	10 minutes

1 Evaluated in the presence of 5% organic soil.

2 Evaluated in the presence of 1% organic soil

Fungicidal Activity: **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** is effective against *Trichophyton mentagrophytes*, the Athlete's foot fungus. Use in locker rooms, dressing rooms, shower and bath areas, exercise facilities or any other hard, non-porous surface.

Deodorizes: **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes, use in the kitchen, bathroom, sink rooms and basements.

APPLICATION INSTRUCTIONS

6/7

Surfaces that are heavy soiled with organic matter must be pre-cleaned prior to using this product.

General Disinfection:

For general disinfection and elimination of bacteria such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Listeria monocytogenes*, Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA) and *Escherichia coli* 0157:H7 the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 2 minutes. The surface may then be wiped dry with a clean towel.

** When used as directed, **AXEN® 30™ Disinfectant, Fungicidal & Virucidal Spray** provides protection from *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* up to 24 hours after initial application. Do not clean treated surface after application if 24 hour protection is expected to be maintained

Fungus Control:

For effective control of fungus such as *Trichophyton mentagrophytes*, the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

Viral Control:

For elimination of Herpes Simplex Type 1 F(1) Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 1 minute. The surface may then be wiped dry with a clean towel.

For the elimination of Influenza A Virus, Hong Kong strain, Rhinovirus R37 Strain 151-1, Polio Virus Type 2 Lansing Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel.

Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV): **Instructions for Cleaning and Decontamination Against HIV** on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids: **Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Apply **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** to area to be treated. The surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds. The surface may then be wiped dry with a clean towel. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

STORAGE AND DISPOSAL	
Storage:	Do not contaminate water, food or feed by storage or disposal.
Disposal:	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.

IN CASE OF EMERGENCY	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.	

Additional language for front panel

7/7

Eliminates Odors
 Eliminates – or – Kills 99.9999% of *Pseudomonas aeruginosa*,
Staphylococcus aureus, *Salmonella choleraesuis*, and *Listeria*
monocytogenes in 30 seconds
 Eliminates – or – Kills 99.9999% of *Staphylococcus aureus* in 30 seconds
 Eliminates – or – Kills 99.9999% of *Salmonella choleraesuis* in 30 seconds
 Eliminates – or – Kills 99.9999% of *Listeria monocytogenes* in 30 seconds
 Eliminates – or – Kills 99.9999% of *Pseudomonas aeruginosa* in 30 seconds
 Kills 99.9999% of germs in 30 seconds*
 Kills germs in 30 seconds*
 Eliminates – or - Kills common household germs
 Eliminates – or - Kills common household germs including *Salmonella*,
Staphylococcus, *Listeria*, and *E. coli*.
 Eliminates – or - Kills *Salmonella*, *Staphylococcus*, *Listeria*, and *E. coli*.
 Eliminates – or – Kills - Bacteria, Fungus and Virus*
 No dulling residue
 Disinfects without bleaching
 No harsh chemical smell
 Odorless
 Disinfects household surfaces
 No Mixing Required
 24 hour protection**

KEY: *= Refer to table

Alternate language for the back panel

Eliminates – or – Kills 99.9999% of *Pseudomonas aeruginosa*,
Staphylococcus aureus, *Salmonella choleraesuis*, and *Listeria*
monocytogenes in 30 seconds
 Eliminates – or – Kills 99.9999% of *Staphylococcus aureus* in 30 seconds
 Eliminates – or – Kills 99.9999% of *Salmonella choleraesuis* in 30 seconds
 Eliminates – or – Kills 99.9999% of *Listeria monocytogenes* in 30 seconds
 Eliminates – or – Kills 99.9999% of *Pseudomonas aeruginosa* in 30 seconds
 Kills 99.9999% of germs in 30 seconds*
 Kills germs in 30 seconds*
 24 hour protection**

KEY: *= Refer to table

Optional graphics for back of label (graphics are larger here than they will appear on the label)

