



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OCT 5 2006

Steptoe & Johnson, LLP, Agent for
ETI H20
c/o 1330 Connecticut Avenue, NW
Washington, DC 20036-1795

Attention: Elizabeth Ann Brown, Ph.D.

Subject: Axen30
EPA Registration No. 72977-3
Amendment Application Date: July 14, 2006
EPA Received Date: July 14, 2006

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable.

- Delete the signal word "Caution"

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

If you have any question or comments concerning this letter, please contact me at (703) 308 6341 or Portia Jenkins at (703) 308-6230.

Sincerely,

A handwritten signature in cursive script that reads "M Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
Antimicrobials Division (7510)

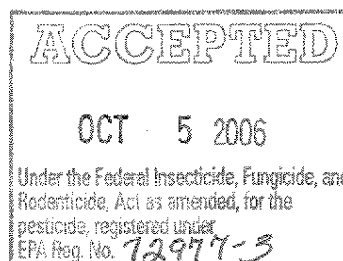
Enclosure

7-14-2006

Axen® 30

Disinfectant, Fungicide & Virucide*

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



Manufactured by ETI H2O
A Division of Innovative Medical
Services
1725 Gillespie Way
El Cajon, CA 92020
EPA REG. No. 72977-3
EPA EST. No. 72977-CA-001

Active Ingredient

Silver†	0.003%
Citric Acid	4.840%
Other Ingredients	95.157%
Total	100.000%

† Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

NOTE: Bracketed information is optional wording for product specific labels

DIRECTIONS FOR USE

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

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to kill 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] and [restrooms].

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 including [walls], [floors], [counters], [sinks], [exterior toilet surfaces], [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].

[This product] can be used in can be used in [homes], [schools], [nurseries], [daycare centers], [playrooms], [playground and/or recreational facilities], [washrooms], [kitchens], [restrooms and/or bathrooms], [school buses].

Use to disinfect the following hard, non-porous surfaces: [children's toys], [toys] [toy box(s)], [diaper pail(s)], [diaper changing table(s)], [bathroom and/or kitchen counter(s)], [desk(s)], [play table(s)], [computer keyboard], [telephone] [doorknob(s)], [jungle gym(s)], [playhouse(s)], [child car seat], [stroller(s)], [crib(s)], [playpen(s)], [activity center(s)], [tanning beds];

[FAST], [EASY], [EFFECTIVE]
General Information

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray successfully killed the following organisms under AOAC protocols (In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions):

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> O157:H7 ¹	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
‡*HIV type 1- Strain HTLV III B 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]

ACCEPTED
 OCT 5 2006
 Under the Federal Insecticide, Fungicide, and
 Herbicide Act as amended, for the
 pesticide registered under
 EPA Reg. No. 72977-3

NOTE: Bracketed information is optional wording for product specific labels

7-14-2006

[**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, and exercise facilities.]

[**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

Pre-clean surfaces prior to using this product.

General Disinfection:

For general disinfection and control of the bacteria *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Listeria monocytogenes*, Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA) and *Escherichia coli* O157: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.

Fungus Control:

For effective control of the fungus *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.

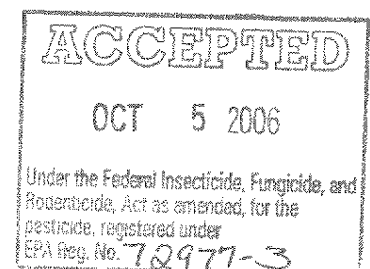
*Viral Control:

To kill Herpes Simplex Type 1 F(1) Strain 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. This contact time will not control all organisms listed on this label. Refer to application instructions for other organisms. **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.

KEY: The following language will be printed on the label of products intended to be sold to health facilities:

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 normally 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 or high level disinfection.



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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.	

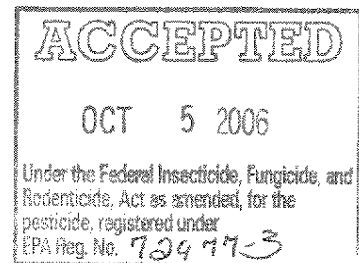
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Under the Federal Insecticide, Fungicide, and
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pesticide, registered under
EPA Reg. No. 72977-3

Additional language for front or back panel

Kills *Staphylococcus aureus* in 30 seconds‡
 Kills *Salmonella choleraesuis* in 30 seconds‡
 Kills *Listeria monocytogenes* in 30 seconds‡
 Kills *Pseudomonas aeruginosa* in 30 seconds‡
 Kills germs in 30 seconds‡
 Kills common household germs
 Kills common household germs including *Salmonella*, *Staphylococcus*,
Listeria, and *E. coli*.
 Kills [*Salmonella*], [*Staphylococcus*], [*Listeria*], and [*E. coli*].
 Kills - Bacteria, Fungus and Virus*
 [Kills] [Eliminates] MRSA
 [Kills] [Eliminates] Methicillin Resistant Staph
 [Kills] [Eliminates] Methicillin Resistant *Staphylococcus aureus*
 [Kills] [Eliminates] VRE
 [Kills] [Eliminates] Vancomycin-resistant Enterococcus
 [Kills] [Eliminates] Vancomycin resistant Enterococcus faecium
 [Kills] [Eliminates] HIV
 [Kills] [Eliminates] Herpes Simplex Virus
 [Kills] [Eliminates] Influenza A Virus
 [Kills] [Eliminates] Rhinovirus
 [Kills] [Eliminates] Polio Virus Type
 Silver Formula
 No dulling residue
 Disinfects without bleaching
 No harsh chemical smell
 Odorless
 Disinfects household surfaces
 No Mixing Required
 Powered by [Axenohl®] [SDC 2400] [Axenohl Alternate brand name]
 For daily use
 Patented formula
 Use for a [fresh] [home] [environment] [kitchen]
 Commercial Line
 Industrial Line
 Hospital Line
 Consumer Line
 Retail Line
 Odoban® [Commercial] (use restricted to the trademark owner)

**KEY:**

* = Refer to viruses

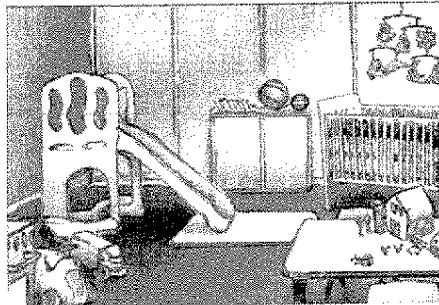
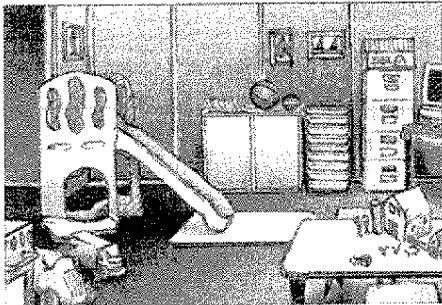
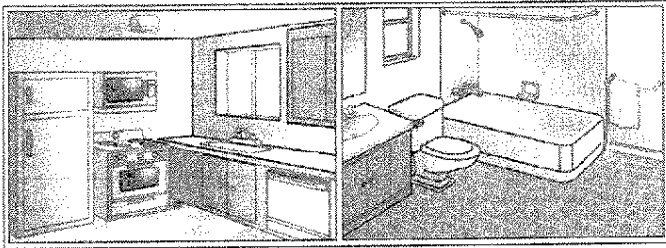
‡ = Refer to organisms controlled with 30 second kill time

Alternate language for the front or back panel

[Formulated for] [Hospitality Environment] [Institutional] [Childcare
 Environments] [Medical & Nursing Environment]

7-14-2006

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



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