



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

March 17, 2004

Elizabeth A. Brown, Ph.D.  
Consultant  
**ChemReg International, LLC**  
Agent for ETI H2O  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192

Subject: **Axen® 30**  
EPA Registration Number 72977-3  
Application dated March 10, 2004

Dear Dr. Brown:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 98-10, FIFRA section 3 (c) 9.

**Proposed Notification:**

- add optional marketing statements

**General Comment:**

Based on a review of the material submitted, the following comment apply.

A copy of the notification has been inserted in your file for future reference.

Should you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.


Sincerely,

A handwritten signature in cursive script that reads "Renae J. Whitaker".

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

Please read instructions on reverse before completing form

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98

 <b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration	OPP Identifier Number
	<input type="checkbox"/> Amendment	
	<input checked="" type="checkbox"/> Other	

**Application for Pesticide - Section I**

1. Company/Product Number 72977-3 4. Company/Product (Name) Axen 30	2. EPA Product Manager Adam Heyward PM # 33	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include ZIP Code) ETI H2O 1725 Gillespie Way El Cajon CA 92020  <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____

**Section - II**

<input type="checkbox"/> Amendment - Explain below  <input type="checkbox"/> Resubmission in response to Agency letter dated _____  <input checked="" type="checkbox"/> Notification - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application  <input type="checkbox"/> Other - Explain below
--	---

**NOTIFICATION**  
 Date Reviewed: 3-12-04  
 Reviewed By: Elizabeth K



**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.) Notification of Other Labeling Revisions per PR Notice 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

**Section III**

1. Material This Product Will be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
<b>*Certification must be submitted</b>		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4-32 oz; 1-220 gallon		5. Location of label directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
Manner in Which Label is Affixed to Product			<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		

**Section IV**

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Elizabeth Anne Brown	Title Authorized Agent	Telephone No. (Include Area Code) 703-492-7905			
<b>Certification</b>					6. Date Application Received  (Stamped)  <div style="border: 2px solid black; padding: 5px; text-align: center;"> <b>RECEIVED</b>            3-12-04   </div>
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law					
2. Signature 		3. Title Authorized Agent			
4. Typed Name Elizabeth Anne Brown		5. Date March 10, 2004			

# ChemReg

INTERNATIONAL, LLC

3/9

1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905  
MAIN: 703-492-0445  
Fax: 703-492-0668

E-MAIL: brown@chemreg.com  
WEB SITES: www.chemreg.com  
www.pesticide.net

**ELIZABETH A. BROWN, PH.D.**

*Hand Delivery*

March 10, 2004

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

Attention: Adam Heyward (PM 34)

NOTIFICATION  
Date Reviewed: 3-12-04  
Reviewed By: B. Whiteaker

Re: Axen 30, EPA Reg. No. 72977-3  
Notification of other labeling revisions per PR Notice 98-10

Dear Adam:

On behalf of our client, ETI H2O, we are notifying for optional marketing statements for "Axen 30." This submission is in full compliance with the notification procedure as identified in PR Notice 98-10. This is a resubmission of the notification originally submitted on December 3, 2003, in accordance with our phone call of March 9, 2004. During that phone call, you requested that this notification be resubmitted and identified that you would expedite acceptance based on your further consideration.

As required by PR Notice 98-10 for notifications for other labeling revisions, enclosed please find the following:

1. Application Form (8570-1), including the PR Notice 98-10 Certification Statement
2. One copy of the product labeling with each of the changes highlighted.

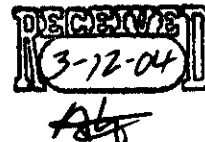
Please let me know if you have any questions about the enclosed items. Please either fax me a copy of the Agency's acceptance of this notification or contact me to pick up a stamped, accepted copy.

Regards,

*Elizabeth Anne Brown*

Elizabeth Anne Brown

cc: ETI H2O



**CONSULTANTS TO SUCCESS<sup>SM</sup>**

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.

4/9

# Axen® 30

Disinfectant, Fungicide & Virucide\*

NOTIFICATION  
Date Reviewed: 3-12-04  
Reviewed By: RWH/MSK

NOTIFICATION  
Date Reviewed: 3-12-04  
Reviewed By: RWH/MSK

(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  
Net Vol. 32 oz.

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

† Electrolytically generated Silver ions  
KEEP OUT OF REACH OF CHILDREN

**CAUTION**

RECEIVED  
3-12-04  
RW

### 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 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), (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).

(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> <sup>1</sup>	30 seconds
<i>Staphylococcus aureus</i> <sup>1</sup>	30 seconds
<i>Salmonella choleraesuis</i> <sup>1</sup>	30 seconds
<i>Listeria monocytogenes</i> <sup>1</sup>	30 seconds
Vancomycin resistant <i>Enterococcus faecium</i> <sup>1</sup>	2 minutes
Methicillin resistant <i>Staphylococcus aureus</i> <sup>1</sup>	2 minutes
<i>Escherichia coli</i> O157:H7 <sup>1</sup>	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
HIV type 1- Strain HTLV IIIB <sup>1</sup>	30 seconds
Herpes Simplex Type 1 VR-733 F(1) Strain <sup>2</sup>	1 minute
Influenza A VR-544, Hong Kong strain <sup>2</sup>	10 minutes
Rhinovirus R37 VR-1147, Strain 151-1 <sup>2</sup>	10 minutes
Polio Type 2, VR-1002, Lansing Strain <sup>2</sup>	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, 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

Surfaces that are heavy soiled with organic matter must be pre-cleaned 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* 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.

### 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. **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.

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

<b>IN CASE OF EMERGENCY</b>	
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**

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\*

No dulling residue

Disinfects without bleaching

No harsh chemical smell

Odorless

Disinfects household surfaces

No Mixing Required

**KEY: \*= Refer to table**

**Alternate language for the 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\*

**KEY: \*= Refer to table**

**Alternate language for the front or back panel**

Hospitality Environment

Institutional

Childcare Environments

Medical & Nursing Environment



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

