

72977-3

C 0310412010

1/9

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



Office of Pesticide Programs

MAR - 4 2010

ETI H2O, INC.
725 Gillespie Way
El Cajon, CA 92020

AGENT: Steptoe and Johnson, LLP
330 Connecticut Avenue, N.W.
Washington, D. C. 20036-1795

Attention: Elizabeth Brown, Ph.D.

Subject: Axen 30
EPA Registration No. 72977-3
Amendment Dated February 1, 2010

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9).

Proposed Notification

- To correct wording under the HIV section

General Comments

Based on a review of the submitted material, the following comments apply:

The Notification dated February 3, 2010 is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)

<p style="margin: 0;">United States Environmental Protection Agency Washington, DC 20460</p>	<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	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Axen30	PM # 33	
5. Name and Address of Applicant (Include ZIP Code) ETI H2O 1725 Gillespie Way El Cajon, CA 92020		6. Expedited Review. 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 _____
<input type="checkbox"/> Check if this is a new address		

Section - II

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

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

"This notification is consistent with the provisions of 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 18U.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 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."

Please send electronic response to E.A. Brown, email eabrown@steptoe.com.

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 checked="" type="checkbox"/> Metal	<input type="checkbox"/> Plastic
*Certification must be submitted		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; 1-275 gallon		5. Location of label directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. 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 Steptoe & Johnson, LLP Authorized agent	Telephone No. (Include Area Code) 202-419-5166
Certification 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		6. Date Application Received
2. Signature <i>Elizabeth Anne Brown</i>	3. Title Steptoe & Johnson, LLP Authorized Agent	(Stamped)
4. Typed Name Elizabeth Anne Brown	5. Date February 3, 2010	

WRITER'S DIRECT DIAL
202.419.5166

1330 Connecticut Avenue, NW
Washington, DC 20036-1795
Tel 202.429.3000
Fax 202.429.3902
steptoe.com

February 3, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Marshall Swindell (PM 33)

Re: Notification for Axen30, EPA Reg. No. 72977-3 to Correct Wording

Dear Marshall:

In accordance with PR Notice 98-10, Section II.N., enclosed please find a Notification to correct the wording regarding what protective clothing should be worn while cleaning surfaces and items soiled with blood or body fluids contaminated with the HIV virus. This does not affect any EPA-required precautionary wording regarding the use of the product or the directions for use of this product. This change is being submitted via notification per the direction of Dennis Edwards, who should be contacted in case of any questions.

Enclosed with this application please find EPA Form 8570-1 (application form), and one copy of the proposed labeling with changes highlighted.

Please provide an electronic response on this notification to me at eabrown@steptoe.com.

Sincerely,



Elizabeth Anne Brown, Ph.D.
Technical & Regulatory Analyst

cc: ETI H2O

Axen® 30

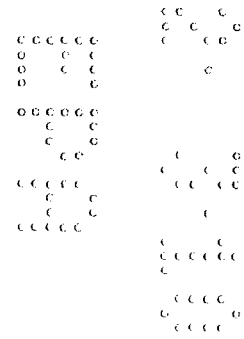
Disinfectant, Fungicide & Virucide*

[Disinfects and Deodorizes]
[Restaurants] • [Hospitals] • [Schools] • [Homes] • [Offices] • [Trucks] •
[Trailers] • [Shipping Containers]
• [Rail Cars]

Manufactured by ETI H2O
A Division of PURE Bioscience
1725 Gillespie Way
El Cajon, CA 92020
EPA REG. No. 72977-3
EPA EST. No. 72977-CA-001
Net Vol.

Active Ingredient	
Silver†	0.003%
Citric Acid	4.846%
Other Ingredients	<u>95.151%</u>
Total	100.000%
† Electrolytically generated Silver ions	

KEEP OUT OF REACH OF CHILDREN



NOTE: [Bracketed] text is optional wording ***Bold/italicized text is information only and not part of the label.***

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 ***Choose from the list below***

- | | | | |
|---------------------------|---------------------------|-------------------------|-------------------------|
| homes | patient transfer vehicles | kitchens | laundromats |
| offices | hotels | restrooms | school buses |
| hospitals | restaurants | bathrooms | cars [autos] |
| nursing homes | bars | washrooms | RV [mobile home] |
| medical clinics | supermarket[grocery | laundry rooms | trucks |
| dental clinics | store] | bedrooms | trailers |
| pharmacies | schools | basements | shipping containers |
| laboratories | colleges | garage(s) | rail cars |
| funeral homes | dorm rooms [dormitories] | workshops | subways |
| veterinary clinics | churches | attics | trains |
| animal shelters | shelters | locker rooms | airplanes |
| kennels | day care facilities | exercise facilities | ships |
| cages | daycare centers | gyms | cruise ships |
| stables | nurseries | beauty shops or salons) | busses |
| catteries | playrooms | barber shops | other public |
| animal transport vehicles | playgrounds | spas | transportation vehicles |
| ambulances | recreational facilities | health clubs | |

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 ***Choose from the list below***

- | | | | |
|--------------------------|---------------------|------------------------------|------------------------|
| walls | light switch covers | lab benches | activity centers |
| floors | telephones | children's toys | diaper pails |
| counters | appliances | toys | diaper changing tables |
| cabinets [cabinet | stove tops | toy boxes | potty[training] seats |
| handles] | bed frames | play tables | laundry hampers |
| sinks | wheelchairs | jungle gyms | bathroom counters |
| tubs | over-bed tables | playhouses | kitchen counters |
| exterior toilet [urinal] | examination tables | child car seats, hard | desks |
| surfaces | waste containers | surfaces only | grocery carts |
| faucet handles | tables | booster chairs [seats] | computer keyboard(s) |
| showers | chairs | strollers [stroller handles] | tanning beds |
| doorknobs | patio furniture | cribs | |
| handrails | equipment tables | playpens | |

NOTE: [Bracketed] text is optional wording *Bold/italicized text is information only and not part of the label.*

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>	30 seconds
‡ <i>Salmonella enterica</i>	30 seconds
<i>Staphylococcus aureus</i>	2 minutes
<i>Listeria monocytogenes</i>	2 minutes
Vancomycin resistant <i>Enterococcus faecium</i> (VRE)	2 minutes
Methicillin resistant <i>Staphylococcus aureus</i> (MRSA)	2 minutes
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA)	2 minutes
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA-PVL)	2 minutes
<i>Escherichia coli</i> O157:H7	2 minutes
<i>Acinetobacter baumannii</i>	2 minutes
<i>Campylobacter jejuni</i>	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
‡*HIV type 1- Strain HTLV IIIB	30 seconds
*Herpes Simplex Type 1 VR-733 F(1) Strain	1 minute
*Rotavirus	3 minutes
*Human Coronavirus	3 minutes
*Norovirus [as Feline Calicivirus]	10 minutes
*Avian Influenza A	10 minutes
*Influenza A [VR-544, Hong Kong strain]	10 minutes
*Rhinovirus [R37 VR-1147, Strain 151-1]	10 minutes
*Polio Type 2, [VR-1002, Lansing Strain]	10 minutes

[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

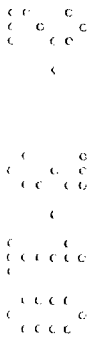
Pre-clean surfaces prior to using this product.

General Disinfection:

For general disinfection and control of the bacteria *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella enterica*, *Listeria monocytogenes*, Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA), Community Associated Methicillin resistant *Staphylococcus aureus* (CA-MRSA), Community Associated Methicillin resistant *Staphylococcus aureus* (CA-MRSA-PVL), *Escherichia coli* O157:H7, *Acinetobacter baumannii* and *Campylobacter jejuni* 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 residual protection from *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* up to 24 hours after initial application. Do not [touch] [contact] treated surface after application if residual protection is to be maintained.

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.



NOTE: [Bracketed] text is optional wording **Bold/italicized text is information only and not part of the label.**

Additional language for front or back panel

Kills *Salmonella enterica* [in 30 seconds[†]]
 Kills *Pseudomonas aeruginosa* [in 30 seconds[†]]
 Kills *Staphylococcus aureus*
 Kills *Listeria monocytogenes*
 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*
 Disinfects common household surfaces
 Can help reduce the risk [danger] of cross contamination
 [Kills] [Eliminates] *Acinetobacter baumannii* [in 2 minutes]
 [Kills] [Eliminates] *Campylobacter jejuni* [in 2 minutes]
 [Kills] [Eliminates] MRSA
 [Kills] [Eliminates] Methicillin Resistant Staph
 [Kills] [Eliminates] Methicillin Resistant *Staphylococcus aureus*
 [Kills] [Eliminates] CA-MRSA
 [Kills] [Eliminates] PVL-MRSA
 [Kills] [Eliminates] Community Associated MRSA [Methicillin Resistant *Staphylococcus aureus*]
 [Kills] [Eliminates] VRE
 [Kills] [Eliminates] Vancomycin-resistant Enterococcus
 [Kills] [Eliminates] Vancomycin resistant Enterococcus faecium
 [Kills] [Eliminates] HIV [in 30 seconds[†]]
 [Kills] [Eliminates] Herpes Simplex Virus
 [Kills] [Eliminates] Influenza A Virus
 [Kills] [Eliminates] Rhinovirus
 [Kills] [Eliminates] Polio Virus Type 1
 [Kills] [Eliminates] Rotavirus
 [Kills] [Eliminates] Human Coronavirus
 [Kills] [Eliminates] Norovirus virus [as Feline Calicivirus]
 [Kills] [Eliminates] Avian Influenza A on pre-cleaned environmental hard surfaces
 [Patented] Silver [ion] Formula
 No dulling residue
 Disinfects without bleaching
 No harsh chemical smell
 Odorless
 Disinfects household surfaces
 No Mixing Required
 Powered by [Axenoh!®] [SDC 2400] [Axenoh! Alternate brand name]
 For daily use
 Patented formula
 [U.S. Patent(s) 6,197,814 ; 6,583,176, [additional patent numbers as issued]
 Other patents pending
 Use for a [fresh] [home] [environment] [kitchen]
 Commercial Line
 Industrial Line
 Hospital Line
 Consumer Line
 Retail Line
 Freight Line
 Janitorial Line
 Janitorial Disinfectant
 Odoban® [Commercial], [Janitorial], [Earth Choice] (use restricted to the trademark owner)
 [FAST], [EASY], [EFFECTIVE]
 This product has demonstrated effectiveness against Influenza A Virus [and Avian Influenza A Virus] and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
 Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
 Kills Pandemic 2009 H1N1 influenza A virus.

KEY:

*-Refer to viruses †-Refer to organisms controlled with 30 second kill time

NOTE: [Bracketed] text is optional wording ***Bold/italicized text is information only and not part of the label.***

