

72977-3

11/10/2009

1/10

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



Office of Pesticide Programs

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

NOV 10 2009

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 October 23, 2009

This will acknowledge receipt of your notification to add additional Influenza A virus per Agency's Guidance Issued October 21, 2009 (Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)) to the product label, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

The Notification dated October 23, 2009 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)

Please read instructions on reverse before completing form

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

	United States	<input type="checkbox"/>	Registration	OPP Identifier Number
	Environmental Protection Agency	<input type="checkbox"/>	Amendment	
	Washington, DC 20460	<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 Additional Influenza A virus per PR Notice 95-2, PR Notice 98-10, and Agency Guidance of 10/21/2009:

"This notification is consistent with the provisions of PR Notice 95-2, 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 PR Notice 95-2, 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 ebrown@step toe.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 type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
*Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
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 checked="" type="checkbox"/> Paper glued	<input type="checkbox"/> Other _____	
		<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 Step toe & Johnson, LLP Authorized agent	Telephone No. (Include Area Code) 202-419-5196
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 (Stamped)
2. Signature <i>Elizabeth Anne Brown</i>	3. Title Step toe & Johnson, LLP Authorized Agent	
4. Typed Name Elizabeth Anne Brown	5. Date October 23, 2009	

Axen[®] 30

Disinfectant, Fungicide & Virucide*

[Disinfects and Deodorizes]

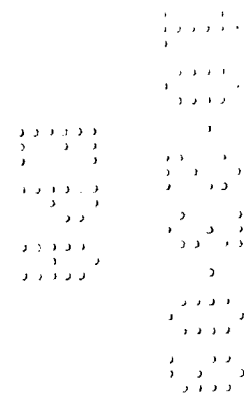
- [Restaurants] • [Hospitals] • [Schools] • [Homes] • [Offices] • [Trucks] •
- [Trailers] • [Shipping Containers]
- [Rail Cars]

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.

<u>Active Ingredient</u>	
Silver [†]	0.003%
Citric Acid	4.846%
<u>Other Ingredients</u>	<u>95.151%</u>
<u>Total</u>	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

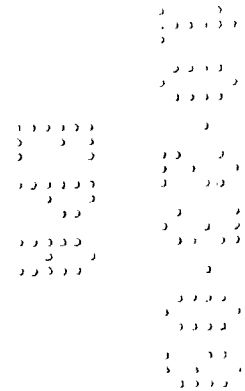
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

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

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 | telephones | children's toys | diaper pails |
| floors | appliances | toys | diaper changing tables |
| counters | stove tops | toy boxes | potty[training] seats |
| cabinets [cabinet 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 keyboards |
| showers | chairs | strollers [stroller handles] | tanning beds |
| doorknobs | patio furniture | cribs | |
| handrails | equipment tables | playpens | |
| light switch covers | lab benches | activity centers | |



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.***

KEY:

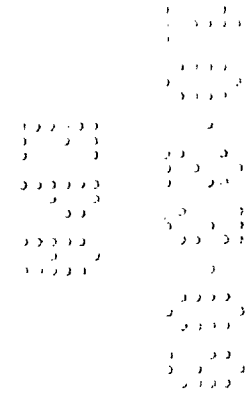
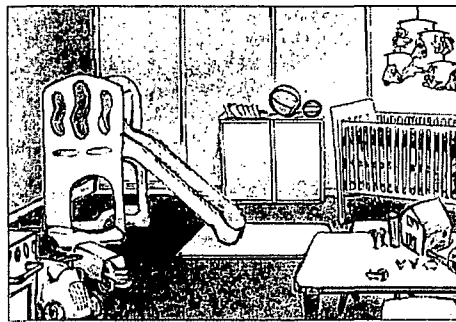
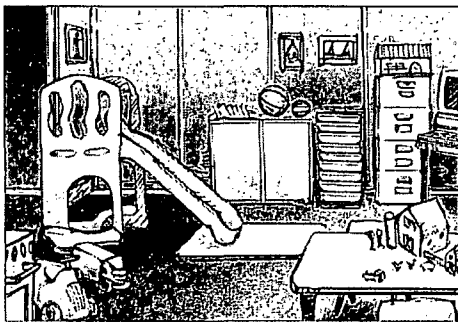
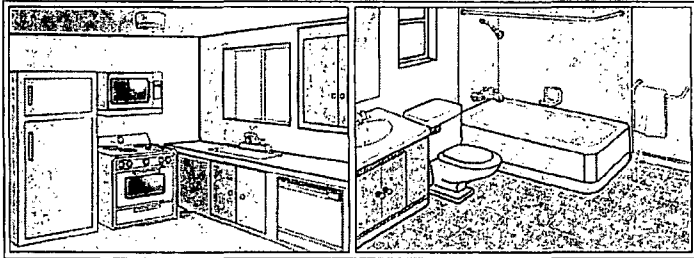
*-Refer to viruses

±-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]

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



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

