

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)), 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

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

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

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

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.***

***Viral Control:**

To kill Herpes Simplex Type 1 [F(1) Strain], Rotavirus, Human Coronavirus, Norovirus [as Feline Calicivirus], Avian Influenza A, Influenza A Virus [Hong Kong strain], Rhinovirus [R37 Strain 151-1] and 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

Note to Reviewer: The following are optional phrases as outlined in the EPA's Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)

[Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. Axen30 [This product] is a broad-spectrum hard surface disinfectant that has been shown to be effective 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).]

Axen30 [This product] has demonstrated effectiveness against Influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.]

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 ordinarily 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.

STORAGE AND DISPOSAL	
Storage:	Do not contaminate water, food or feed by storage or disposal.
Pesticide Disposal:	Nonrefillable Container. Do not reuse container. If empty: Place in trash or offer for recycling if available. 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.	

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 [Axenohl®] [SDC 2400] [Axenohl 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.](#)

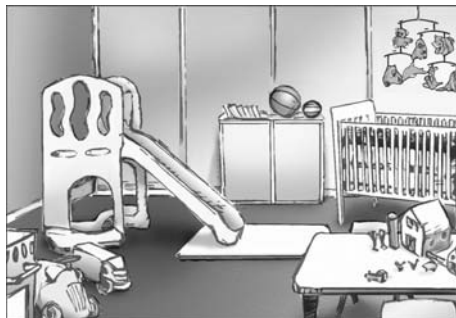
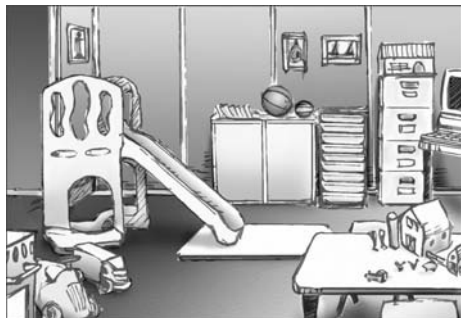
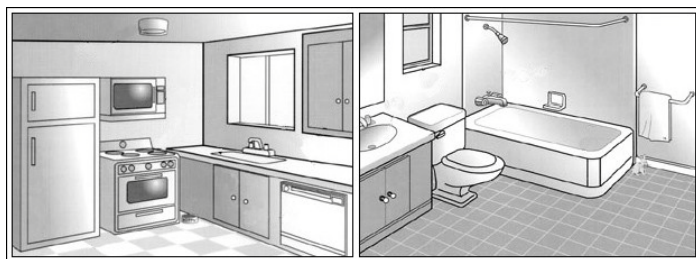
KEY:

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

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)



THE FOLLOWING TABLE IS OPTIONAL TEXT:

[

Organism	ID
<i>Pseudomonas aeruginosa</i>	ATCC#15442
<i>Staphylococcus aureus</i>	ATCC#6538
<i>Salmonella enterica</i>	ATCC#10708
<i>Listeria monocytogenes</i>	ATCC#19111
Vancomycin resistant <i>Enterococcus faecium</i> (VRE)	ATCC#700221
Methicillin resistant <i>Staphylococcus aureus</i> (MRSA)	ATCC#700698
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA)	NRS123, USA 400
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA-PVL)	NRS 192
<i>Escherichia coli</i> O157:H7	ATCC#43888
<i>Acinetobacter baumannii</i>	ATCC#19606
<i>Campylobacter jejuni</i>	ATCC#29428
Trichophyton mentagrophytes (Athlete's Foot Fungus)	ATCC#9533
*HIV type 1- Strain HTLV IIIB	HTLV-IIIB
*Herpes Simplex Type 1 VR-733 F(1) Strain	ATCC VR-733
*Rotavirus	Strain WA, Ottawa
*Human Coronavirus	ATCC VR-740
* Norovirus [as Feline Calicivirus]	ATCC VR-782
*Avian Influenza A	ATCC VR-2072
*Influenza A [VR-544, Hong Kong strain]	ATCC VR-544
*Rhinovirus [R37 VR-1147, Strain 151-1]	ATCC VR-1147
*Polio Type 2, [VR-1002, Lansing Strain]	ATCC VR-1002

]

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