

72977-3

2/19/2009

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

FEB 19 2009

ETI H2O
A Division of PURE Bioscience
1725 Gillespie Way
El Cajon, CA 92020

Attention: Elizabeth Brown, Agent
Steptoe and Johnson LLP

Subject: Axen 30
EPA Registration No. 72977-3
Amendment Dated August 25, 2008

The amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended to upgrade your product labeling claims supported by testing submitted for the Antimicrobials Testing Program is acceptable.

Make the following labeling changes:

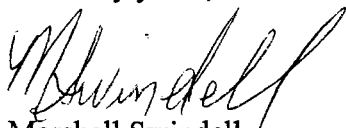
1. On page five of the label, delete the statement "Kills germs in 30 seconds". This claim is not supported by data as there must be 30 second data against bacterial, viruses, and pathogenic fungi.
2. The medical device use claim on the proposed label differs slightly from the statement set forth in PR Notice 94-4. The medical device use claim on the proposed label must be revised to read: "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 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."

3. Delete the “residual activity for up to 24 hours after initial application claim”. Numerous requests dating back to 2004 and 2006 have been made for the removal of this statement. Efficacy data is required to support a residual claim.

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

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

Sincerely yours,



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]

ACCEPTED
WITH COMMENTS
Re: EPA Letter Dated:

FEB 19 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

72977-3

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	95.151%
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 keyboards |
| showers | chairs | strollers [stroller handles] | tanning beds |
| doorknobs | patio furniture | cribs | |
| handrails | equipment tables | playpens | |

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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.

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.

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***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

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.

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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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 common household germs~~
 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 [Axeohl®] [SDC 2400] [Axeohl 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]

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KEY:

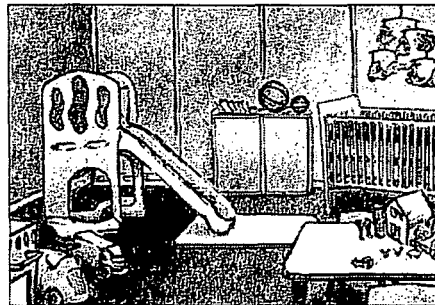
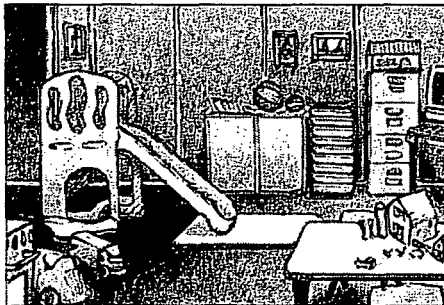
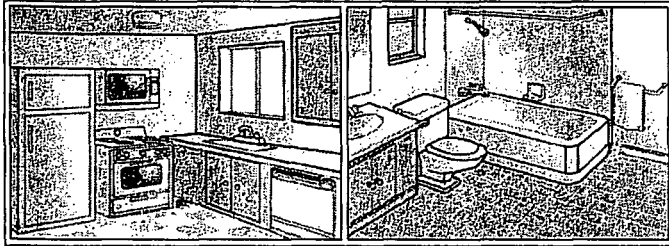
*-Refer to viruses ‡-Refer to organisms controlled with 30 second kill time

Alternate language for the front or back panel

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

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

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



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On EPA Letter Dated:

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72977-3

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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

]

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 Fungicide, and Rodenticide Act
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 registration number 72977-3

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