



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT 12 2007

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Elizabeth Anne Brown
Authorized Agent for,
ETI H2O
1725 Gillespie Way
El Cajon, CA 92020

Mail to: Attn: Elizabeth Anne Brown
Steptoe and Johnson LLP
1330 Connecticut Avenue, N.W.
Washington, D.C. 20036-1795

Subject: Axen 30
EPA Registration Number 72977-3
Your Amendment Dated May 24th, 2007
EPA Received Date May 24th, 2007

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to modify the formulation process and add additional organisms to the product labeling, is acceptable.

CHEMISTRY

The modification of the Formulation Process for the silver and citric acid based end-use disinfectant Axen 30, is acceptable.

The modified Formulation Process on the basis of the product chemistry of this amendment, met all the study requirements for OPPTS 830.1650.

EFFICACY

The submitted efficacy data support the use of the product, Axen 30, as a disinfectant on hard, non-porous surfaces against the following organisms under the following conditions:

Acinetobacter baumannii	2 and 5 minutes	MRID 471380-08
Campylobacter jejuni	2 and 5 minutes	MRID 471380-10

156.10(a)(5)(vii), and therefore imply heightened efficacy. The Agency considers antimicrobial pesticides to be unique because of the critical nature of the threat to public health that may result from ineffective use of products due to obsolete or misleading labeling. As a result, any reference to claims of effectiveness against Clostridium difficile (vegetative cells) OR Clostridium difficile (without having support data against C. difficile spores) are unacceptable.

All references to claims against Clostridium difficile must be removed from the product labeling.

To address the growing need for products in hospital/medical setting, the Agency is moving expeditiously to develop an appropriate test system and performance standards for Clostridium difficile (spores).

The proposed label states that the product, Axen 30, is effective against Respiratory syncytial virus. Data was not provided to support this claim. The data matrix does not identify an efficacy study for this virus. Remove the reference to Respiratory syncytial virus, or provide efficacy data that fully meet DIS/TSS-7 requirements.

The Agency has stated the “kill-time” and “contact time” are synonymous terms. Therefore, the contact time and kill time must be consistent, as demonstrated by the efficacy studies submitted.

Please make the following labeling revisions:

✓ Change “Salmonella choleraesuis” to read “Salmonella enterica” throughout the proposed label.

Revise the organism listing on page 3 of the proposed label to include information about testing in the presence of an organic soil load as follows:

- Human coronavirus²
- Rotavirus²
- Avian Influenza A²
- Norwalk virus(as Feline calicivirus)
- [1 Evaluated in the presence of 5% organic soil]
- [2 Evaluated in the presence of 1% organic soil]

On page 2 of the proposed label, change child car seats” to read “child car seats, hard surfaces only.”

On page 2 of the proposed label, change “lights switch covers” to read “light switch covers”.

✓ The list of ATCC numbers or other company designation numbers must be provided in on the following locations:

- On the Data Matrix
- On the master label (as optional text) with the listing of the organisms claimed; or
- As the final page of the master label (as optional text).

Clostridium difficile(vegetative)	30seconds and 2 minutes	MRID 471380-02.
Staphylococcus aureus	2 and 5 minutes	MRID 471380-01
-CA-MRSA		
Staphylococcus aureus	2 and 5 minutes	MRID 471380-06
-CA-MRSA,PVL Positive		

The submitted efficacy data support the use of the product, Axen 30, as a disinfectant with virucidal activity on hard, non-porous surfaces against the following microorganisms in the presence of a 1% organic soil load for the contact time listed:

Avian Influenza A (H3N2) virus	10 minutes	MRID 471380-09
Human coromavirus	3 and 10 minutes	MRID 471380-10
Rotavirus	3 and 10 minutes	MRID 471380-07

The submitted efficacy data (MRID No. 471380-03 and -04) support the use of the product, Axen 30, as a disinfectant with virucidal activity on hard, non-porous surfaces against Feline Calicivirus (surrogate for Norovirus) in the presence of a 5% organic soil load for a contact time of 10 minutes.

LABELING

The proposed label claims for the product, Axen 30, is an effective disinfectant for use on hard, non-porous surfaces against the following microorganisms for the listed contact times:

Acinetobacter baumannii	2 minutes
Campylobacter	2 minutes
Staphylococcus aureus-CA-MSRA	2 minutes
Staphylococcus aureus-CA-MRSA, PVL Positive	2 minutes
Avian Influenza A	10 minutes
Human coronavirus	3 minutes
Norwalk virus (as Feline calivirus)	10 minutes
Rotavirus	3 mintues

Please remove all references indicating that Human coronavirus is a "SARS surrogate". Acceptance of the data to support a label claim for Human coronavirus does not in any way support a label claims for disinfectant against the causative agent for Severe Acute Respiratory Syndrome(SARS). Furthermore, claims for CA-MRSA are not acceptable, rather claims for MRSA, with appropriate designation are accepted by the Agency.

Please note that claims for effectiveness against Clostridium difficile (vegetative cells) at a contact time of 30 seconds is unacceptable. The Agency has re-evaluated its acceptance of Clostridium difficile(vegetative cells) on previously accepted claims and requests for new claims. Peer-reviewed scientific literature and case studies have consistently demonstrated that the C.difficile spore is the source of Clostridium difficile-associated disease(CDAD), and is an immediate public health claims against the vegetative form of C.difficile are true statements, but are used in such a way as to give a false or misleading impression to the purchaser (40 CFR

On the proposed label, change "0" to "O" in Escherichia coli.

As consistent with the appropriate nomenclature, the correct designation is "Norovirus" for "Norwalk virus" (Norovirus was recently approved as the official genus name for the group of viruses provisionally described as "Norwalk-like viruses" (NLV) (<http://www.cdc.gov/ncidod/dhqp/id-norovirusFS.html>).

The use of this product on children's toys requires a potable water rinse. Revise the proposed labeling to include this information.

A copy of the efficacy review is enclosed for your records.

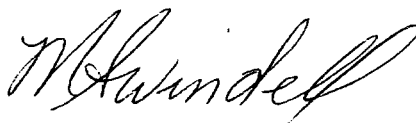
A stamped copy of the labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/re-registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar product to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510P)

Axen® 30

Disinfectant, Fungicide & Virucide*

[Disinfects and Deodorizes]

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

ACCEPTED
with **COMMENTS**
EPA Letter Dated:

OCT 12 2007

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	<u>95.151%</u>
Total	100.000%

[†] Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

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

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

ACCEPTED
with COMMENTS
EPA Letter Dated:

JUL 12 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
amended, for the pesticide
registered under EPA Reg. No. 72997-3

NOTE: [Bracketed] text is optional wording Underlined text is new text. 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
<u>†Pseudomonas aeruginosa</u> ¹	30 seconds
<u>†Staphylococcus aureus</u> ¹	30 seconds
<u>†Salmonella choleraesuis</u> ¹	30 seconds
<u>†Listeria monocytogenes</u> ¹	30 seconds
Vancomycin resistant <i>Enterococcus faecium</i> ¹ (VRE)	2 minutes
Methicillin resistant <i>Staphylococcus aureus</i> ¹ (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 Positive)	2 minutes
<i>Escherichia coli</i> 0157:H7 ¹	2 minutes
<i>Acinetobacter baumannii</i>	2 minutes
<i>Campylobacter jejuni</i>	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
<u>†*HIV type 1- Strain HTLV IIIB</u> ¹	30 seconds
*Herpes Simplex Type 1 VR-733 F(1) Strain ²	1 minute
*Rotavirus	3 minutes
*Human Coronavirus	3 minutes
*Norwalk virus [as Feline Calicivirus]	10 minutes
*Avian Influenza A	10 minutes
*Influenza A [VR-544, Hong Kong strain] ²	10 minutes
*Rhinovirus [R37 VR-1147, Strain 151-1] ²	10 minutes
*Polio Type 2, [VR-1002, Lansing Strain] ²	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

Pre-clean surfaces 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), Community Associated Methicillin resistant *Staphylococcus aureus* (CA-MRSA), Community Associated Methicillin resistant *Staphylococcus aureus* (CA-MRSA, PVL Positive), *Escherichia coli* 0157: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 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.

ACCEPTED
with COMMENTS
EPA Letter Dated:

OCT 12 2007

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

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 7299

2010

***Viral Control:**

To kill Herpes Simplex Type 1 [F(1) Strain], Rotavirus, Human Coronavirus, Norwalk virus [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.	

ACCEPTED
with COMMENTS
EPA Letter Dated:

OCT 12 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **72997-3**

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

Additional language for front or 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[‡]
 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
 [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] Norwalk 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
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]

ACCEPTED
with COMMENTS
EPA Letter Dated:

OCT 12 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
amendment to the pesticide,
registered under EPA Reg. No. 72911-3

KEY:

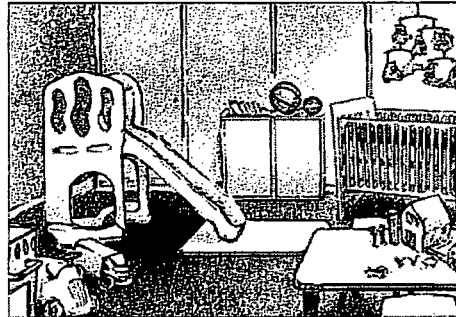
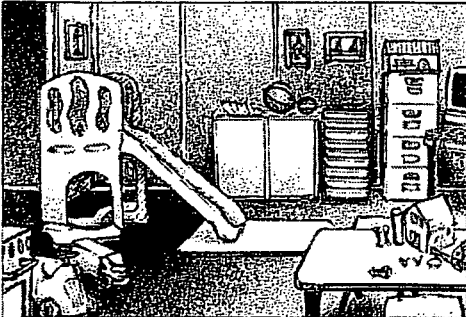
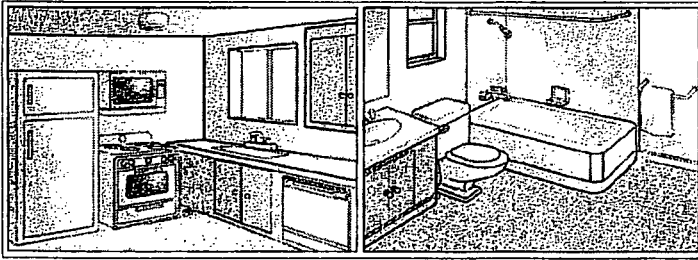
*-Refer to viruses ‡-Refer to organisms controlled with 30 second kill time

Alternate language for the front or back panel

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

NOTE: [Bracketed] text is optional wording Underlined text is new text. *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)



ACCEPTED
with COMMENTS
EPA Letter Dated:

OCT 12 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 72977-3

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