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

Mail to: Steptoe and Johnson
1330 Connecticut Ave., N.W.
Washington, DC 20036-1796

Subject: EPA Registration Number 72977-3
Your Amendment dated January 15th, 2010
EPA Received Date January 15, 2010

The amendment referred to above, submitted in connection with registration under section 3 (c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. The Agency has no objection to your company’s addition of the following microorganisms to the Axen 30 label: Influenza A (H1N1), Swine Influenza (H1N1), Respiratory Syncytial Virus [RSV], Adenovirus Type 2, Equine Herpes Virus Type 1, and Murine Norovirus. The Agency further notes that the CSFs dated 01/12/10, for the basic and alternate #s (1 and 2) formulations, are acceptable.

A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

If you have any questions concerning this letter, please contact Abigail Downs at (703) 305-5259.

Sincerely,

Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
Antimicrobials Division (7510P)
Axen® 30
Disinfectant, Fungicide & Virucide*

[Disinfects and Deodorizes]
[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

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

ACCEPTED with COMMENTS
EPA Letter Dated:
JUN 4 2010

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  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
- offices
- hospitals
- nursing homes
- medical clinics
- dental clinics
- pharmacies
- laboratories
- funeral homes
- veterinary clinics
- animal shelters
- kennels
- cages
- stables
- catteries
- animal transport vehicles
- ambulances

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
- floors
- counters
- cabinets (cabinet handles)
- sinks
- tubs
- exterior toilet (urinal) surfaces
- faucet handles
- showers
- doorknobs
- handrails
- patient transfer vehicles
- hotels
- restaurants
- bars
- supermarket (grocery store)
- schools
- colleges
- dorm rooms (dormitories)
- churches
- shelters
- day care facilities
- daycare centers
- nurseries
- playrooms
- gyms
- attics
- locker rooms
- exercise facilities
- response centers
- wheelchairs
- over-bed tables
- examination tables
- waste containers
- tables
- chairs
- patio furniture
- equipment tables
- lab benches
- children's toys
- toy boxes
- play tables
- jungle gyms
- playhouses
- child car seats, hard surfaces only
- booster chairs (seats)
- strollers (stroller handles)
- cribs
- playpens
- activity centers
- diaper pails
- diaper changing tables
- potty training seats
- laundry hampers
- bathroom counters
- kitchen counters
- desks
- grocery carts
- computer keyboards
- tanning beds

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

ACCEPTED with COMMENTS
EPA Letter Dated: JUN 4 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 729773
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):

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

[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 test is information only and not part of the label.

ACCEPTED with COMMENTS
EPA Letter Dated: JUN 4 2010

The Federal Insecticide, Fungicide and Rodenticide Act as a Vaccine for the pesticide,
Registered under EPA Reg. No. 72977-3
**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 and 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 mucus 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.

ACCEPTED
with COMMENTS
EPA Letter Dated:

JUN 4 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 72977-3
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
  - *Salmonella*, *Staphylococcus*, *Listeria*, and *E. coli.*
- Kills *Bacteria, Fungus and Virus* (in 30 seconds)
- Disinfects common household surfaces
- Can help reduce the risk of cross contamination
- Kills *Acinetobacter baumannii* (in 2 minutes)
- Kills *Campylobacter jejuni* (in 2 minutes)
- Kills *MRSA*
- Kills *Methicillin Resistant Staph*
- Kills *Methicillin Resistant Staphylococcus aureus*
- Kills *CA-MRSA*
- Kills *PVL-MRSA*
- Kills *Community Associated MRSA* (Methicillin Resistant *Staphylococcus aureus*)
- Kills *VRE*
- Kills *Vancomycin-resistant Enterococcus*
- Kills *Vancomycin-resistant Enterococcus faecium*
- Kills *HIV* (in 30 seconds)
- Kills *Herpes Simplex Virus*
- Kills *Influenza A Virus*
- Kills *Rhinovirus*
- Kills *Polio Virus Type 1*
- Kills *Rotavirus*
- Kills *Human Coronavirus*
- Kills *Norovirus virus* (as Feline Calicivirus)
- Kills *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

[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 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.
**THE FOLLOWING TABLE IS OPTIONAL TEXT:**

<table>
<thead>
<tr>
<th>Organism</th>
<th>ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>ATCC#15442</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>ATCC#6536</td>
</tr>
<tr>
<td>Salmonella enterica</td>
<td>ATCC#10768</td>
</tr>
<tr>
<td>Listeria monocytogenes</td>
<td>ATCC#19111</td>
</tr>
<tr>
<td>Vancomycin resistant Enterococcus faecium (VRE)</td>
<td>ATCC#700221</td>
</tr>
<tr>
<td>Methicillin resistant Staphylococcus aureus (MRSA)</td>
<td>ATCC#700698</td>
</tr>
<tr>
<td>Community Associated Methicillin resistant Staphylococcus aureus (CA-MRSA-PVL)</td>
<td>NRS123, USA 400</td>
</tr>
<tr>
<td>Community Associated Methicillin resistant Staphylococcus aureus (CA-MRSA-PVL)</td>
<td>NRS 192</td>
</tr>
<tr>
<td>Escherichia coli O157:H7</td>
<td>ATCC#43988</td>
</tr>
<tr>
<td>Acinetobacter baumannii</td>
<td>ATCC#19806</td>
</tr>
<tr>
<td>Campylobacter jejuni</td>
<td>ATCC#29428</td>
</tr>
<tr>
<td>Trichophyton mentagrophytes (Athlete's Foot Fungus)</td>
<td>ATCC#9533</td>
</tr>
<tr>
<td>*HIV type 1 - Strain HTLV IIB</td>
<td>HTLV-IIB</td>
</tr>
<tr>
<td>*Herpes Simplex Type 1 VR-733 F(1) Strain</td>
<td>ATCC VR-733</td>
</tr>
<tr>
<td>*Rotavirus</td>
<td>Strain WA, Ottawa</td>
</tr>
<tr>
<td>*Human Coronavirus</td>
<td>ATCC VR-740</td>
</tr>
<tr>
<td>*Norovirus [as Feline Calicivirus]</td>
<td>ATCC VR-782</td>
</tr>
<tr>
<td>*Avian Influenza A</td>
<td>ATCC VR-2072</td>
</tr>
<tr>
<td>*Influenza A [VR-544, Hong Kong strain]</td>
<td>ATCC VR-544</td>
</tr>
<tr>
<td>*Rhinovirus [R37 VR-1147, Strain 151-1]</td>
<td>ATCC VR-1147</td>
</tr>
<tr>
<td>*Polio Type 2, [VR-1002, Lansing Strain]</td>
<td>ATCC VR-1002</td>
</tr>
</tbody>
</table>

**ACCEPTED with COMMENTS**

EPA Letter Dated: JUN 4 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 72917-3

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