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



EPA United States Environmental Protection Office of Pesticide Programs Agency

MAR - 4 2010

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

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 February 1, 2010

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9).

Proposed Notification

- To correct wording under the HIV section

General Comments

Based on a review of the submitted material, the following comments apply:

The Notification dated February 3, 2010 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 Swindel

Product Manager 33

Regulatory Management Branch 1 Antimicrobials Division (7510P)

Please read instructions on reverse before completing form

United States

| Registration |
|--------------|
| Amendment |

| Form Approved, OMB No. 2070-0060, Approval expires 5-31-98 | | | | | | | |
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| Registration | OPP Identifier Number | | | | | | |

| EPA Environmenta | ency | Amendme | nt | | | |
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| 4. Company/Product (Name) | PM# | | X No | ne | Restricted | |
| Axen30 5. Name and Address of Applicant (Include ZIP Code | 1 | 33 6. Expedited Revie | w In accordance | | BA Section | n 3(c)(3) |
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| El Cajon, CA 92020 | | EPA Reg No. | | | | |
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| X Notification – Explain below | | Other – Expla | ain below | | | |
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| "This notification is consistent with the provisions of 96 labeling or the confidential statement of formula of this | s product. I understar | nd that it is a violation of | of 18U.S.C. Sec. | 1001 to v | villfully mak | e any false |
| statement to EPA. I further understand that if this notification of FIFRA and I may be subject to enforcement | | | | | this produc | t may be in |
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| Please send electronic response to E.A. Brown, email | eabrown@steptoe.c | <u>ж.</u> | | | ç c | 0 |
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| Contact Person (Complete items directly below for Name | Title | iduai to de contacted, | | | <i>is applicati</i> nclude Are | |
| Elizabeth Anne Brown | 1 1 | ohnson, LLP agent | 202-419 | | | u 00u0, |
| | ertification | | | 6. | Date App | |
| I certify that the statements I have made on this form an | | | • | | Received | 1 |
| I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law | | | | | | |
| Signature | 3. Title | | | | (Sta | mped) |
| • | ohnson, LLP | | | | | |
| Elizabeth and Brown | Authorized / | Ayem | | | | |
| 4. Typed Name | 5. Date February 3, | 2010 | | | | |

WRITER'S DIRECT DIAL 202.419.5166

1330 Connecticut Avenue, NW Washington, DC 20036-1795 Tel 202.429.3000 Fax 202.429.3902 steptoe.com

February 3, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention:

Marshall Swindell (PM 33)

Re:

Notification for Axen30, EPA Reg. No. 72977-3 to Correct Wording

Dear Marshall:

In accordance with PR Notice 98-10, Section II.N., enclosed please find a Notification to correct the wording regarding what protective clothing should be worn while cleaning surfaces and items soiled with blood or body fluids contaminated with the HIV virus. This does not affect any EPA-required precautionary wording regarding the use of the product or the directions for use of this product. This change is being submitted via notification per the direction of Dennis Edwards, who should be contacted in case of any questions.

Enclosed with this application please find EPA Form 8570-1 (application form), and one copy of the proposed labeling with changes highlighted.

Please provide an electronic response on this notification to me at eabrown@steptoe.com.

Sincerely,

Elizabeth Anne Brown, Ph.D.

Technical & Regulatory Analyst

cc: ETI H2O

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. **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



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

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

supermarket[grocery store1 schools colleges churches shelters day care facilities daycare centers nurseries playrooms animal transport vehicles playgrounds ambulances

dorm rooms [dormitories] recreational facilities

patient transfer vehicles

hotels

bars

restaurants

kitchens restrooms bathrooms washrooms laundry rooms bedrooms basements garage(s) workshops attics locker rooms exercise facilities gyms beauty shops or salons)

barber shops spas health clubs

laundromats school buses cars [autos] RV [mobile home] trucks

trailers

shipping containers rail cars subways trains airplanes ships cruise ships busses other public

transportation vehicles

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

light switch covers telephones appliances stove tops bed frames wheelchairs over-bed tables examination tables waste containers tables chairs patio furniture equipment tables

lab benches children's toys 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

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 |
|--|------------|
| ‡Pseudomonas aeruginosa | 30 seconds |
| ‡Salmonella enterica | 30 seconds |
| Staphylococcus aureus | 2 minutes |
| Listeria monocytogenes | 2 minutes |
| Vancomycin resistant Enterococcus faecium (VRE) | 2 minutes |
| Methicillin resistant Staphylococcus aureus (MRSA) | 2 minutes |
| Community Associated Methicillin resistant Staphylococcus aureus (CA-MRSA) | 2 minutes |
| Community Associated Methicillin resistant Staphylococcus aureus (CA-MRSA-PVL) | 2 minutes |
| Escherichia coli O157:H7 | 2 minutes |
| Acinetobacter baumannii | 2 minutes |
| Campylobacter jejuni | 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 aufeus (CA-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® 30TM 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.

*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 H1N1are 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 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 | Nonrefillable Container. Do not reuse container. If empty: Place in trash or offer for | | |
| Disposal: | 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.





Deleted: or

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] Vanocomycin-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

[

]

THE FOLLOWING TABLE IS OPTIONAL TEXT:

-Organism ATCC#15442 Pseudomonas aeruginosa ATCC#6538 Staphylococcus aureus ATCC#10708 Salmonella enterica Listeria monocytogenes ATCC#19111 Vancomycin resistant Enterococcus faecium (VRE) ATCC#700221 Methicillin resistant Staphylococcus aureus (MRSA) ATCC#700698 Community Associated Methicillin resistant Staphylococcus aureus (CA-MRSA) NRS123, USA 400 Community Associated Methicillin resistant Staphylococcus aureus (CA-MRSA-NRS 192 Escherichia coli O157:H7 ATCC#43888 Acinetobacter baumannii ATCC#19606 ATCC#29428 Campylobacter jejuni 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