

72977-4

8/6/2009

1 of 9



U.S. ENVIRONMENTAL PROTECTION  
AGENCY  
Office of Pesticide Programs  
Antimicrobials Division (7510C)  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460

EPA Reg.  
Number:  
72977-4

Date of Issuance:  
**AUG 0 6 2009**

Term of Issuance:

Name of Pesticide Product: **Axen 50**

**NOTICE OF PESTICIDE:**

- Registration
- Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

**ETI H2O, Inc.  
1725 Gillespie Way  
El Cajon, CA 92020**

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.


This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(B) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

- a. Add the phrase "EPA Registration Number 72977-4."

Signature of Approving Official:

  
**Marshall Swindell**  
Product Manager-33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Date:

**AUG 0 6 2009**

20f9

The revised Confidential Statement of Formula dated January 8, 2007, is acceptable.

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

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

Sincerely,



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

Enclosure: (Stamped Labeling)

3 of 9

Axen50  
EPA Reg. No.: 72977-U  
Revised Draft: July 29, 2009

# Axen50

[Sanitizer for Food Contact Surfaces]  
[Food Contact Surface Sanitizer]

### Active Ingredients

Silver* .....	0.005%
Citric Acid .....	5.000%
Other Ingredients .....	<u>94.995%</u>
Total .....	100.000%

\*electrolytically generated silver ions stabilized in citric acid as silver dihydrogen citrate

**KEEP OUT OF REACH OF CHILDREN**

[This statement may appear on the front or back of the label]

EPA Reg. No. 72977-

EPA Est. No. (insert establishment number here)

Net Contents: (insert container net contents here)

Manufactured by: ETI H2O, a division of PURE Bioscience  
1725 Gillespie Way, El Cajon, CA 92020

**ACCEPTED**  
**with COMMENTS**  
EPA Letter Dated:

AUG - 6 2009

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 72977-4

4089

**Note to reviewer: The following is considered optional marketing language. Language in [ ] is considered optional or interchangeable.**

[INSERT OPTIONAL MARKETING LANGUAGE ON THIS PAGE]

- |   |  |
|---|--|
| Colorless                                     | Institutional sanitizer  |
| Odorless                                      |  |
| Ready-to-Use [Formula]                        | Patented formula   |
| No mixing required                            | Commercial line  |
| No Rinsing required                           | Institutional line   |
| No Rinse Formula                              | Consumer line  |
| No Rinse sanitizer                            |  |
| Sanitize without rinsing                      | Kills 99.999% of bacteria* [in 60 seconds]                     |
| Contains no [dyes] or [artificial fragrances] | Kills 99.999% of Escherichia coli (E. coli) [in 60 seconds]    |
| For daily [use] [sanitization]                | Kills 99.999% of Staphylococcus aureus (Staph) [in 60 seconds] |
| Eliminated odors caused by bacteria           |  |
| Sanitizes kitchen surfaces                    |  |
| Household sanitizer                           |  |

Powered by [Axenohl]

*(Note to reviewer: Axenohl is the MUP used to make this product. We may insert any registered brand name for the MUP in this phrase)*

- [This product] is an effective sanitizer for use on food contact surfaces in 60 seconds [1 minute].
- For use in [food service], [hospitality],
- For use in [households], [kitchens], [food preparation areas]
- For use in [institutional kitchens], [medical institution kitchen and dining areas], [lodging establishment kitchens and dining areas]
- For sanitizing food processing equipment, dairy and milk processing equipment, sink tops, countertops, refrigerated storage and display equipment and other hard non-porous surfaces.

For use in :

- [Restaurants], [bars], [cafeterias], [institutional kitchens], [fast food operations], [fast food restaurants], [ food preparations areas], [food storage areas], [food establishments],
- [coffee shops], [donut shops], [bagel stores], [pizza parlors], [liquor stores], [delis]
- [kitchens], [Food processing plants], [USDA inspected food-processing facilities], [dairy facilities], [egg processing plants], [meat/poultry processing plants], [meat/poultry producing establishments], [rendering plants]

ACCEPTED  
with COMMENTS  
EPA Letter Dated

AUG - 6 2009

5089

Axen50

EPA Reg. No.: 72977-U

Revised Draft: July 29, 2009

- Processing facilities for: [Food], [fish], [milk], [citrus], [fruit], [vegetables], [wine], [ice cream], [potatoes] and [beverage plants]
- [Cruise ships food contact areas], [buffet counters], [dining halls], [casinos food contact areas],

This product may be used on hard non-porous surfaces such as:

- [Plastic and other non-porous cutting boards], [plastic and other non-porous chopping blocks], [coolers], [ice chests], [refrigerator bins used for meat, vegetables, fruit and eggs], [countertops], [stovetops], [appliances], [ice machines], [highchairs], [picnic tables], [drinking fountains]
- Kitchen equipment such as: [food processors], [blenders], [trash compactors], [meat cutting machines], [meat slicing machines], [bread slicing machines], [Mixing equipment], [Ice machines], [bottled water machines]
- [Citrus processing equipment and holding tanks]

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

AUG - 6 2009

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 72977-4

leaf 9

**Note to reviewer: The following is considered optional marketing language. Language in [ ] is considered optional or interchangeable.**

**AREAS OF USE**

Use [this product] to sanitize hard nonporous food contact surfaces in:

- |  |   |
|--|---|
| Households   | Coffee shops                              |
| Homes  | Donut shops                               |
| Restaurants  | Bagel stores                              |
| Eating establishments                                  | Liquor stores                             |
| Food processing [establishments] [plants] [facilities] | Deli(s) [Delicatessens]                   |
| Beverage plants  | Supermarkets                              |
| Dairies  | Grocery stores                            |
| Kitchen(s)   | Convenience stores                        |
| Dining Room(s)   | Snack Bars                                |
| Lunchroom(s)   | Egg Processing Plants                     |
| Cafeteria(s)   | Food storage areas                        |
| Bars   | Food Prep [Preparation] areas [surfaces]  |
| Institutional Kitchens                                 | Salad Prep [Preparation] areas [surfaces] |
| Fast food operations                                   |   |

**TYPES OF SURFACES**

Use [this product] on hard, non-porous surfaces (ie stainless steel, painted, glazed tile, plastic, glass, glazed porcelain) of

- |                        |                                     |                                |
|------------------------|-------------------------------------|--------------------------------|
| Sinks                  | Counter tops                        | Floors                         |
| Drain [cutting] boards | [counters]                          | Refrigerated storage equipment |
|                        | Baby bottles                        | Refrigerated display equipment |
| Beverage Bars          | Breast Pumps                        | Blenders                       |
| Dairy Cases            | Breast Pump Parts                   | Bottling equipment             |
| Dish racks             | Kitchen appliances                  | Premixing equipment            |
| Dishwasher             | Kitchen sinks                       | Chopping blocks                |
| Drainboards            | Kitchen surfaces                    |                                |
| Food cases             | Lunch boxes [pails]                 | Food processors                |
| Food Contact surfaces  | Pacifiers                           | Ice Chests                     |
| Food trays             | Pet Bowls [dishes] [feeding dishes] | Ice machines                   |
| High chairs            | Salad bars                          |                                |
| High Chair trays       | Snack counters                      |                                |
|                        | Stovetops                           |                                |

**ACCEPTED  
with COMMENTS  
EPA Letter Dated:**

AUG - 6 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 72977-4

7099

Axen50  
EPA Reg. No.: 72977-U  
Revised Draft: July 29, 2009

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.  
Do not use this product on utensils, dishes or glassware.  
Prolonged contact with this product may cause skin discoloration.

*NOTE TO REVIEWER: Products labeled for residential use will include the following directions for use:*

**[To] Sanitize Food Contact Surfaces**  
Pre clean item [surface] prior to sanitizing.  
Spray, pour or spread [this product] on surface until thoroughly wet. Let stand for 60 seconds [one minute] and wipe with a clean towel or allow to air dry. No rinsing is required.  
\*[This product] kills 99.999% of Escherichia coli [E. coli] and Staphylococcus aureus [Staph].

*NOTE TO REVIEWER: Products labeled for commercial/industrial use will include the following directions for use:*

**To sanitize food contact surfaces**  
or  
**To sanitize food processing equipment and other hard surfaces in food processing locations, dairies, restaurants and bars:**

[Recommended] for sanitizing food processing equipment, dairy equipment, sink tops, countertops, refrigerated storage and display equipment, and other hard nonporous surfaces. Recommended for use in restaurants, dairies, food processing plants [establishments] [facilities] and bars.

[Clean, Rinse Sanitize]  
Prior to application, remove gross food particles and soil by pre-flush or pre-scrape and when necessary, pre-soak. Thoroughly wash objects to be sanitized with a good detergent or cleaner followed by a potable water rinse prior to applying sanitizer. **NO POTABLE WATER RINSE IS ALLOWED AFTER APPLICATION AS A SANITIZER.**

Apply [this product] by spraying or by total immersion. Surfaces must remain wet for 60 seconds [1 minute].

If the [article] surface] can not be washed and rinsed, clean thoroughly in an appropriate fashion prior to sanitizing.

\*[This product] is a ready to use sanitizer that eliminates 99.999% of the following bacteria in 60 seconds:  
Escherichia coli (ATCC 11229) Staphylococcus aureus

-OR-

**ACCEPTED**  
**with COMMENTS**  
EPA Letter Dated: **AUG - 6 2009**  
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 72977-U

8089

Prior to use in a federally inspected meat and poultry plants and dairies, food products and packaging materials must be removed from the room or carefully protected. A potable water rinse is not permitted following the use of this product as a sanitizer on previously cleaned hard, non-porous surfaces, provided that the surfaces are adequately drained before contact with food so that little or no residue remains.

Apply product to pre-cleaned hard surfaces thoroughly wetting surfaces with a cloth, mop, sponge, sprayer or by immersion. For spray applications, spray product 6 to 8 inches from surface using a trigger sprayer or coarse pump. Surfaces should remain wet for 1 minute followed by adequate draining and air drying.

\*[This product] is a ready to use sanitizer that eliminates 99.999% of the following bacteria in 60 seconds:

Escherichia coli (ATCC 11229)

Staphylococcus aureus

**DIRECTIONS FOR SANITIZING FOOD PROCESSING EQUIPMENT AND FOOD CONTACT ARTICLES REGULATED BY 21CFR Sec. 178.1010: b(22), c(17)**

1. Scrape flush or presoak articles to remove gross food particles and soil.
2. Thoroughly wash articles in an appropriate detergent or cleaner.
3. Rinse articles thoroughly with potable water.
4. Sanitize articles by immersion in [this product] for 60 seconds. Articles too large for immersion should be thoroughly wetted with {this product] by rinsing, spraying or swabbing.
5. Remove immersed items from solution to drain and air dry. Non-immersed items should also be allowed to air dry.

**U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS CLEANING AND SANITIZING:**

Equipment and articles shall be thoroughly pre-flushed or pre-scraped and pre-soaked when necessary to remove gross food particles and soil.

1. Thoroughly wash equipment and articles in a hot detergent solution. Rinse equipment thoroughly with potable water.
2. Sanitize equipment by immersion for 60 seconds at a temperature of 75°.
3. For equipment and articles that are too large to immerse, apply [this product] by rinsing, spraying or swabbing until thoroughly wetted.
4. Allow sanitized surfaces to drain and air dry. No potable water rinse is allowed.

**ACCEPTED**  
with **COMMENTS**  
EPA Letter Dated:

AUG - 6 2009



**WISCONSIN STATE DIVISION OF HEALTH  
DIRECTIONS FOR EATING ESTABLISHMENTS**

1. Scrape and pre-wash articles whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with potable water
4. Sanitize in [this product] without diluting. Immerse all articles for at least one minute or for contact time specified by governing sanitary code.
5. Place sanitized articles on a rack or drain board to air dry.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196.13 of the Wisconsin Administrative Code.

**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.

**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.

**ACCEPTED  
with COMMENTS  
EPA Letter Dated:**

AUG - 6 2009

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 72977-4