

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

JUL 0 9 2009

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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, D.C. 20036-1796

Subject: Steptoe and Johnson

EPA Registration Number 72977-1 Your Amendment Dated April 16<sup>th</sup>, 2009 EPA Received Date April 16<sup>th</sup>, 2009

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to modify the sources of the starting material, add a new alternate process, revise the basic and alternate Confidential Statements of Formula to reflect the revised suppliers and addresses, and revise and update the product labeling, is acceptable.

The requirements as per PR Notice 91-2 have been satisfied. The nominal concentration of the active ingredients, silver and citric acid, as shown in the updated basic Confidential Statement of Formula and Alternate formulation #1, agreed with the percentages declared on the product labeling. Additionally, the proposed new Alternate Formulation #2, dated 3/30/09, met all the requirements of PR Notice 91-2.

The upper and lower certified limits for both the active and inert ingredients are accepted.

The active and inert ingredients utilized in the proposed updated and new formulations are cleared for use in pesticide formulations.

The updated Group A product chemistry data is acceptable.

A stamped copy of labeling is enclosed for your records.

A copy of the efficacy reviews dated 09/13/07 is enclosed.

If you have any 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(7510C)

April 15, 2009

## **AXENOHL®**

Stabilized Ionic Silver

# For Use in the Manufacture Of Antimicrobial Products For Commercial, Institutional and Home Use

#### **Active Ingredient**

Silver\* 0.24%
Citric Acid 20.66%
Other Ingredients 79.10%

Total 100.00%

## KEEP OUT OF REACH OF CHILDREN CAUTION

SEE SIDE PANEL FOR PRECAUTIONARY STATEMENTS

EPA REG. No. 72977-1 EPA EST. No. 72977-CA-001

Manufactured by ETI H<sub>2</sub>O,

A Division of <u>PURE Bioscience</u>

1725 Gillespie Way El Cajon, CA 92020 **Deleted:** Innovative Medical Services

#### [Batch number]

ACCEPTED with COMMENTS EPA Letter Dated:

JUL - 9 2009

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

NOTE TO REVIEWER: [Bracketed text] is optional wording. Bold and italicized text is informational only and not part of the label. Batch number may be placed on the label or on the container itself.

<sup>\*</sup> Electrolytically generated Silver ions

#### PRECAUTIONARY STATEMENTS

### HAZARDSTO HUMANS AND DOMESTIC ANIMALS CAUTION

	FIRST AID			
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>			
HOT LINE NUMBER				
	product container or label with you when calling a poison control center or doctor, or going ent. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment			

#### **ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish and aquatic invertebrates

information.

This statement will be used on any refillable container.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

<u>Pesticide Storage:</u> Store in a cool, dry area away from direct sunlight at temperatures above freezing.

Store in in original container

Pesticide Disposal: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a national Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Container Handling: Refillable Container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container before final disposal, empty the remaining contents from this container into a mix tank or storage tank. Fill the container about 1/4 full with solvent used in the end use product. Replace and tighten closures. Agitate vigorously or recirculate water with a pump for 2 minutes. Pour or pump rinsate into mix tank or rinsate collection system for later use or disposal, Repeat this rinsing procedure two more times.

ACCEPTED with COMMENTS EPA Letter Dated:

JUL - 9 2009

Under the Federal Insecticide,

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Tegistered finder EPA Reg. No. 73977-/

#### This statement will be used on any nonrefillable container

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry area away from direct sunlight at temperatures above freezing. Store in in original container

Pesticide Disposal: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry). Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a national Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Container Handling: Nonrefillable Container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Offer for recycling if available,

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For Manufacturing Use Only:

For formulation of antimicrobial end use products for the following uses:

Cleaning products, specialty industrial products, products for commercial, institutional and industrial premises and equipment, or products for use in indoor residential premises.

Formulators using this product are responsible for obtaining registrations for their own end use products. This product may be used to formulate products for specific uses not listed on this label if the formulator has complied with US EPA data requirements regarding the support of such uses

US Patents [insert applicable US patent number(s)] Other patents pending Made in the USA [may include US Flag symbol]

> ACCEPTED with COMMENTS EPA Letter Dated:

> > JUL - 9 2009

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

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Deleted: STORAGE AND DISPOSAL¶ Storage

Deleted: This product is intended for use in manufacturing disinfectant products. Formulators are responsible for obtaining registrations for their own end use products.¶

Deleted: For Manufacturing Use Only: Dilute 1 part of Axenohi product with 199 parts of 4.76% citric acid in water.

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Storage	Do not contai	not contaminate water, food or feed by storage or disposal.		
Disposal	ponds, estua national Pollu authority has containing thi treatment pla of the EPA. Container D	Pesticide Disposal: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a national Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.  Container Disposal: Triple rinse. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local		

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