72977-5

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U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Antimicrobials Division (7510C)	EPA Reg. Number: 72977-5	Date of Issuance: NOV. 2 5 2008	
1200 Pennsylvania Avenue NW Washington, D.C. 20460	Term of Issuance:		
NOTICE OF PESTICIDE: x Registration	gistration Name of Pesticide Product:		
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 here Insecticide, Fungicide and Rodenticide Act.	eby registered/reregist	tered under the Federal	
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)(A) provided that you:			
 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. Revise the "EPA Registration Number to read, "EPA Reg. No. 72977-5".			
Signature of Approving Official: Marshall Swindell Product Manager Team-33 Regulatory Management Branch I Antimicrobials Division (7510P)	Date:	<u>N 2 5 2008</u>	
EPA Form 8570-6	<u>.</u>		

Page 2 EPA Registration No. 72977-5

b. The submitted efficacy data (MRID #475200-01 and 475200-02) <u>do not</u> <u>support</u> the use of the tested product, Axen 30, as a disinfectant with bactericidal activity against Staphylococcus aureus and Listeria monocytogenes on pre-cleaned, hard, nonporous surfaces for a <u>30-second</u> contact time. However, the above data supports the use of the tested product as a disinfectant with bactericidal activity against Staphylococcus aureus and Listeria monocytogenes on pre-cleaned, hard, non-porous surfaces for a 120-second contact time. Refer to the enclosed copy of the "Efficacy Review" for further comments.

3. Submit two (2) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

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.

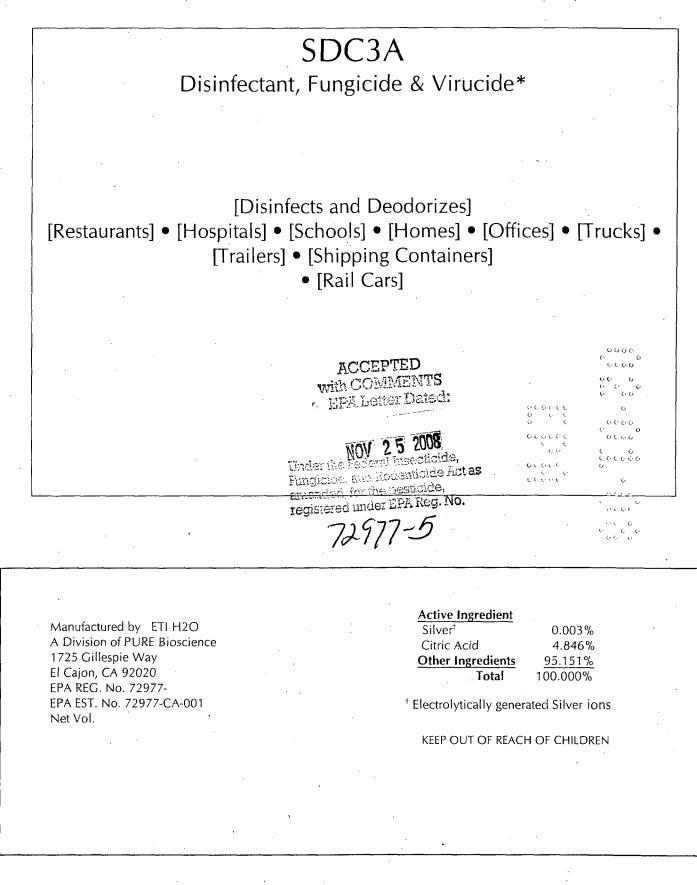
If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,

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

Enclosure

January 28, 2008



*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 **SDC3A** 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 SDC3A to area to be treated. The surface must be completely wet with SDC3A 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.

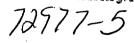
STORAGE AND DISPOSAL		
Storage: Do not contaminate water, food or feed by storage or disposal.		
Disposal:	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.	

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: NOV 25 2008

Under the Federal'Insecticide, Fungionale, and housenticide Act as amended, for the posticide, registered under EPA Reg. No.



DIRECTIONS FOR USE

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

SDC3A is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to kill bacteria, fungus and viruses*, SDC3A should be used on non-porous environmental hard surfaces in **Choose from the list below**

homes	patient transfer vehicles
offices	hotels
hospitals	restaurants
nursing homes	bars
medical clinics	supermarket[grocery store]
dental clinics	schools
pharmacies	colleges
laboratories	dorm rooms [dormitories]
funeral homes	churches
veterinary clinics	shelters
animal shelters	day care facilities
kennels	daycare centers
cages	nurseries
stables	playrooms
catteries	playgrounds
animal transport vehicles	recreational facilities
ambulances	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 0000

6000

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SDC3A 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 control of the second of the

ACCEPTED with COMMENTS EPA Letter Dated:

NOV 2 5 2008

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

General Information

SDC3A 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 ^[1]	30 seconds
tStaphylococcus aureus His	Clance
‡Salmonella enterica ^{III}	30 seconds
Histeria managenes a company a	30 seçon dis
Vancomycin resistant Enterococcus faecium ¹¹ (VRE)	2 minutes
Methicillin resistant Staphylococcus aureus ¹¹ (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 ^{III}	2 minutes
Acinetobacter baumannii	2 minutes
Campylobacter jejuni	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
<i>‡*HIV</i> type 1- Strain HTLV IIIB ^[1]	30 seconds
*Herpes Simplex Type 1 VR-733 F(1) Strain ^[2]	1 minute
*Rotavirus ^[2]	3 minutes
*Human Coronavirus ^[2]	3 minutes
* Norovirus [as Feline Calicivirus] ^[1]	10 minutes
*Avian Influenza A ^[2]	10 minutes
*Influenza A [VR-544, Hong Kong strain] ^[2]	10 minutes
*Rhinovirus [R37 VR-1147, Strain 151-1] ^{12]}	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: SDC3A is effective against Trichophyton mentagrophytes, the Athlete's foot fungus, Use in locker rooms, dressing rooms, shower and bath areas, and exercise facilities.]

IDeodorizes: SDC3A 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 SDC3A for 2 minutes. The surface may then be wiped dry with a clean towel. When used as directed, SDC3A 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 SDC3A for 10 minutes ACCEPTED The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

with COMMENTS EPA Letter Dated:

NOV 2 5 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act a amended, for the pesticide,

NOTE: [Bracketed] text is optional wording. Bold/italicized test is information only and not part of the egistered under EPA Reg. No. label.

Additional language for front or back panel

Kills Staphylac acting autous Tin-10 seconds"
Kills Salmonella enterica [in 30 seconds ^{†]}
Kitter Burner Hugen - 10 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] CA-MRSA-PVL
[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
[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 [Axenohl®] [SDC 2400] [Axenohl Alternate brand name]
. For daily use
Patented formula
[U.S.Patent(s) 6,197,814 ; 6,583,176, 7,261,905
Other patents pending
•
Consumer Line
Retail Line Froight Line
Freight Line Janitorial Line
Janitorial Disinfectant
[FAST], [EASY], [EFFECTIVE]

KEY:

*-Refer to viruses +-Refer to organisms controlled with 30 second kill time Alternate language for the front or back panel

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

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Under the Faderal Inserticide, Functicide, and Rocenticide Act as amended for the periode Act as registered under Epia Reg. No.

THE FOLLOWING TABLE IS OPTIONAL TEXT:

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Organism	ID
Pseudomonas aeruginosa	ATCC#15442
Staphyle Contractions Contraction Contraction	ATTESS
Salmonella enterica ¹	ATCC#10708
Listerin Doppender 2 2 2 2 2	ATCOUNT-
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-PVL)	NRS 192
Escherichia coli O157:H7	ATCC#43888
Acinetobacter baumannii	ATCC#19606
Campylobacter jejuni	ATCC#29428
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

ACCEPTED With COMMENTS

· EPA Letter Dated:

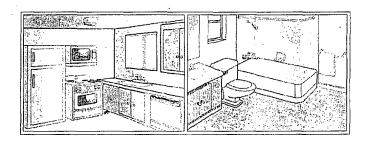
NOV 2 5 2008

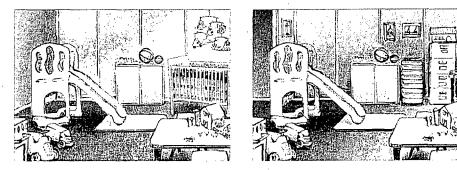
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[Formulated for] [Hospitality Environment] [Institutional] [Childcare Environments] [Medical & Nursing Environment]

Optional graphics for back of label (graphics are larger here than they will appear on the label)





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