

85134-1

07/07/2013

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 7, 2013

Mr. Micah T. Reynolds, Regulatory Consultant to Envirocleanse, LLC
"TSG": Technology Sciences Group
1150 18th Street, Suite 1000
Washington, DC 20036

SUBJECT: FQPA Code 332 Label Update In Accordance With PR Notice 2007-4
PRODUCT NAME: **Anolite**
EPA REGISTRATION NUMBER: **85134-1**
APPLICATION DATE: May 9, 2013
APPLICATION RECEIVED DATE: May 17, 2013

Dear Mr. Reynolds:

This acknowledges receipt of your Notification application, submitted under the provisions of FIFRA section 3(c) 7(A) and PR Notice 98-10.

Pesticide Application:

Envirocleanse, LLC is updating the Storage And Disposal in accordance with PR Notice 2007-4.

General Comments:

Based on the review of the submitted material, the following comments apply. The Notification application is **Acceptable**. A copy of the **accepted** Notification is attached in **Regulatory File Jacket 85134-1**.

If you have questions or comments with regard to this Agency Letter, the please contact Killian Swift via email at Swift.Killian@epa.gov or by telephone at **703-308-6346**. When you are submitting information or data in response to this Agency Letter, please send a copy of this Agency Letter with your response in order to facilitate processing.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Demson Fuller", with a long horizontal line extending to the right.

Demson Fuller,
Acting EPA Product Manager 32
Regulatory Management Branch II
Antimicrobials Division 7510P

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide – Section I

1. Company/Product Number <p style="text-align: center;">85134-1</p>	2. EPA Product Manager <p style="text-align: center;">Mike Mendelsohn</p>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <p>ANOLITE</p>	PM# <p style="text-align: center;">32</p>	
5. Name And Address Of Applicant (Include ZIP Code) <p>Envirocleanse LLC 12999 Murphy Road, Suite A Stafford, Texas 77477</p> <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain Below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

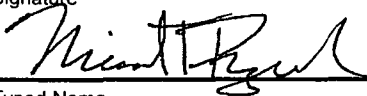
Submission of Label Notification to revise Storage & Disposal instructions per PR Notices 98-10 and 2007-4.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Please confirm receipt with Micah Reynolds: mreynolds@tsqusa.com, via phone (202) 828-8967, or via fax (202) 872-0745.

Section III

1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" No. per Unit Packaging wgt. Container	If "Yes" No. per Unit Packaging wgt. Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container	
		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithographed <input type="checkbox"/> Pager glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name <p>Micah T. Reynolds, Technology Sciences Group, Inc.</p>	Title <p>Senior Regulatory Consultant</p>	Telephone No. (Include Area Code) <p>(202) 828-8967</p>
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamp)
2. Signature 		
3. Title <p>Regulatory Consultant to Envirocleanse LLC</p>		
4. Typed Name <p style="text-align: center;">Micah T. Reynolds</p>		5. Date <p style="text-align: center;">May 9, 2013</p>



Technology Sciences Group Inc.
1150 18th Street, Suite 1000
Washington, DC 20036
Direct: (202) 828-8967
Fax: (202) 872-0745
E-Mail: MReynolds@TSGUSA.com

Micah T. Reynolds
Senior Regulatory Consultant

May 9, 2013

Envirocleanse LLC
Label Notification for ANOLITE;
EPA Reg. No. 85134-1 to revise Storage & Disposal

Mr. Mike Mendelsohn (Acting PM-32)
Antimicrobials Division (7510P)
Office of Pesticide Programs (NOTIF)
U.S. Environmental Protection Agency
Document Processing Center
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202

Dear Mr. Mendelsohn:

Technology Sciences Group, Inc., on behalf of Envirocleanse LLC, herein submits the enclosed label notification for the above referenced product to revise the Storage & Disposal section to include separate instructions for residential/consumer product containers as well as for commercial/institutional product containers. Also revised is the company address that had previously been updated with ITRMD. Please find enclosed the following documents supporting this fast-track amendment:

- 1) EPA Notification Form (EPA Form 8570-1);
- 2) One redline copy of the proposed label with changes indicated;
- 3) Three (3) clean copies of the proposed label.

If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8967 or by e-mail at mreynolds@tsgusa.com.

Sincerely,


Regulatory Consultant to Envirocleanse LLC

Enclosures
CC: P. Bellan (Envirocleanse)

ANOLITE

Ready to Use Disinfectant and Sanitizer for Hard Non-Porous Surfaces

For Commercial and Household Use

Active Ingredient:

Hypochlorous Acid.....	0.025%
Other Ingredients.....	99.975%
Total.....	100.000%

NOTIFICATION

Date Reviewed: _____ July 7, 2013

Reviewed By: _____ Killian B. Swift

Contains 338 ppm Free Available Chlorine

KEEP OUT OF REACH OF CHILDREN

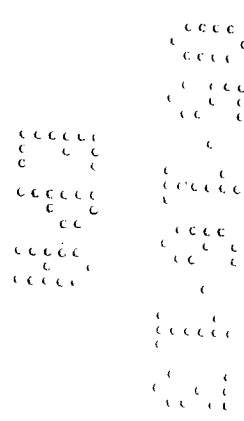
CAUTION

EPA Reg. No: 85134-1
EPA Est. No.: 85134-TX-001

Net Contents:

Manufactured For:
Envirocleanse LLC
12999 Murphy Road, Suite A
Stafford, TX 77477

Batch Code:



This product must be used within 60 days after being produced.

PHYSICAL OR CHEMICAL HAZARDS

Do not use this product with other household or industrial chemicals such as toilet bowl cleaners, rust removers, acids, or products containing ammonia. To do so will release hazardous, irritating gas. Prolonged contact with metal may cause pitting or discoloration.

DIRECTIONS FOR USE

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

(ANOLITE) (this product) is a disinfectant for use on hard non-porous inanimate surfaces. ANOLITE is an oxidized, pH-neutral water based solution that is ready-to-use. When used according to the directions for use, this product disinfects hard, non-porous surfaces including: stainless steel, chrome, glass, vinyl, glazed porcelain, non-porous plastics, enamel and glazed tile.

Disinfection of Hard, Non-porous Surfaces:

(ANOLITE) (this product) can be used to disinfect hard, non-porous surfaces including: countertops, sinks, toilets, tables, chairs, appliances (exterior surfaces), desks, beds (rails, frames, headboards, footboards), floors, computer keyboards, door knobs and similar surfaces. To disinfect, apply (ANOLITE) (this product) to any hard, non-porous surface with a cloth, mop, sponge or coarse sprayer. Wet the surfaces thoroughly and allow surface to remain wet for 10 minutes. Allow treated surface to air dry. Remove gross filth from surfaces before applying this product. Small non-porous objects can also be soaked in ANOLITE without dilution. Allow objects to soak for 10 minutes.

FOR INDOOR USE ON HARD, NON – POROUS SURFACES IN:

- Hotels, motels, Bed & Breakfasts
- Office Buildings
- Fitness Centers
- Locker Rooms
- Restaurants and Bars (non-food contact surfaces)
- Convenience Stores
- Food Processing Plants
- All Schools and Universities
- Indoor Playgrounds
- Day Care Centers
- Nursing Homes
- Cafeterias (non-food contact surfaces)
- Prisons and Correctional Facilities
- Police and Fire Stations
- Hospitals, Health Clinics, Doctors Offices
- Pharmaceutical and Medical Device Producing Establishments
- Homes, Condos, Apartments
- Veterinarian Clinics and Animal Hospitals

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 direct 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 devices prior to sterilization or high level disinfection.

Sanitization of Hard Non-porous Food Contact Surfaces

(ANOLITE) (this product) is an effective sanitizer against gram positive and gram negative bacteria (vegetative forms) such as *Staphylococcus aureus* and *Escherichia coli*.

For use in schools, colleges, industrial and commercial facilities, restaurants, office buildings, recreational facilities, retail and wholesale establishments, food processing facilities, homes, apartments, and condos.

(ANOLITE) (this product) is a sanitizer for use on pre-cleaned non-porous, food contact surfaces including food preparation and storage areas, dishes, glassware, silverware, eating and cooking utensils, plastic and nonporous cutting boards and chopping blocks, other kitchen products used in food preparation, other utensils, coolers, tables, counter tops, sinks, shelves, racks, carts, refrigerators, coolers, glazed tile, refrigerators, microwaves, ovens and stove tops, sinks, appliances, conveyor belts. As well, (ANOLITE) (this product) can be used in direct food application at dose not to exceed 200 ppm FAC of (ANOLITE) (this product). For direct use on food contact surfaces, please dilute (ANOLITE) (this product) 1:1 with tap water, which provides active (ANOLITE) (this product) at 169 ppm FAC.

Prior to application, remove gross food particles and soil by a pre-flush or pre-scrape and when necessary, presoak. Then thoroughly wash or flush objects with a good detergent or compatible cleaner, followed by a potable water rinse before applications of the sanitizing solution.

To sanitize, apply (ANOLITE) (this product) to any hard, non-porous surface with a cloth, mop, sponge or coarse sprayer. Wet the surfaces thoroughly and allow surface to remain wet for 60 seconds. Allow treated surface to air dry. Remove gross filth from surfaces before applying this product.

Oil and Gas Applications

Frac Water – For typical water treatment, mix 0.5 US gallons of (ANOLITE) (this product) with 1000 US gallons of frac water to 0.17 ppm FAC to slow and control the growth of odor and slime producing microorganisms such as sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Sour Wells – For typical well treatment, slug dose 168 US gallons at 338 ppm FAC of (ANOLITE) (this product) into the well bore on a daily basis or weekly basis to control unwanted odor and slime producing microorganisms, reduce hydrogen gas and restore well integrity.

Produced Waters – For typical produced water treatment, mix 21 US gallons of (ANOLITE) (this product) with 979 US gallons of injection water to 7.1 ppm FAC to control unwanted odor and slime causing microorganisms.

Heater Treaters, Hydrocarbon Storage Facilities & Gas Storage Wells – For typical storage facility treatment, mix 126 US gallons of (ANOLITE) (this product) at 338 ppm FAC into the water phase of the mixed hydrocarbon/water system to control odor and slime causing bacteria, reduce the formation of hydrogen sulfide and reduce corrosion of the storage tanks.

Water Flood Injection Water – For typical water flood injection water treatment, mix 21 US gallons of (ANOLITE) (this product) with 979 US gallons of injection water to 7.1 ppm FAC to control odor and slime causing bacteria in pipelines.

Oil and Gas Transmission Lines – For typical transmission line treatment, slug dose 210 US gallons at 338 ppm FAC of (ANOLITE) (this product) into the transmission line on a daily or weekly basis to control microorganisms such as SRB's, reduce microbiologically influenced corrosion (MIC) and remove the slime and any sessile bacteria which can degrade the pipeline integrity.

Note: Upon opening this container, record the date on the container. If the product is transferred to spray bottles or other containers, record the same date on the secondary container. HPDE, PET or glass containers are recommended for secondary container storage. (ANOLITE) (this product) may be used 60 days after production. After 60 days, discard any remaining product in accordance with local, state and federal regulations.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal, or cleaning of equipment.

(Note to reviewer: The following text for residential/household containers.)

Storage: Store (ANOLITE) (this product) in its original sealed container at room temperature, away from direct sunlight and heat to avoid deterioration.

Pesticide Disposal and Container Handling: Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

(Note to reviewer: The following text for commercial/institutional products. Product is non-dilutable.)

Pesticide Storage: Store (ANOLITE) (this product) in its original sealed container at room temperature, away from direct sunlight and heat to avoid deterioration.

Pesticide Disposal: Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

WARRANTY

Envirocleanse LLC warrants that this product conforms to the product specification on this label and is reasonable fit for the purposes set forth in the Directions for Use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MECHANABILITY IS MADE.



OPTIONAL LABEL CLAIMS:

Non-corrosive

No dilution or mixing required

Ready to Use

Disinfection claims

Kills bacteria* on hard non-porous surfaces in 10 minutes.

* *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), and *Salmonella enterica* (ATCC 10708), *Escherichia coli* (ATCC 11229)

Organism Name	ATCC numbers and/or strains
<i>Staphylococcus aureus</i>	ATCC 6538
<i>Pseudomonas aeruginosa</i>	ATCC 15442
<i>Salmonella enterica</i>	ATCC 10708
<i>Escherichia coli</i>	ATCC 11229
H1 N1 A/Swine/1976/31 , ATCC VR-99	ATCC VR-99

Kills *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Salmonella enterica* on treated surfaces.

Kills *S. aureus*, *P. aeruginosa*, *S. enterica*, and H1 N1 A/Swine/1976/31 (ATCC VR-99) virus on treated surfaces

Kills H1 N1 A/Swine/1976/31 (ATCC VR-99) virus (formerly called swine flu) on treated surfaces.

Kills H1 N1 A/Swine/1976/31 (ATCC VR-99) virus on treated surfaces.

Sanitization claims

Kills *E. coli* and *S. aureus* on treated food contact surfaces in 60 seconds.

Kills *Escherichia coli* and *Staphylococcus aureus* on treated surfaces in 60 seconds.

An effective sanitizer for use on food contact surfaces.

(ANOLITE) (this product) is recommended for use as a sanitizer on dishes, glassware and utensils.

