

82341-1

9/23/2014

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SEP 23 2014

Mr. Tim W. Shields, Director
IET, Inc.
4235 Commerce Street
Little River, South Carolina 29566

Subject: Alternate Brand Names per PR Notice 98-10
Ecaflo Anolyte
EPA Registration Number: **82341-1**
Application Date: August 19, 2014
Application Receipt: August 21, 2014

Dear Mr. Shields:

This acknowledges receipt of your Notification application, submitted under the provisions of FIFRA 3(c) 9 and PR Notice 98-10.

Purpose of the Notification:

IET, Inc. is adding the following Alternate Brand Name to EPA Reg. No. 82341-1:

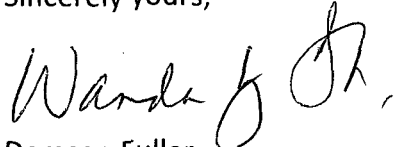
CleanBeyond Excel

General Comments:

Based on the review of the information submitted, the following comments apply. The Notification is not acceptable. The Brand Name is misleading as it implies that the Product may be used beyond the Use Sites listed on the Product Label (e.g., soft surfaces). A copy of the Notification is attached in **Regulatory File Jacket 82341-1** for future reference.

If you have questions or concerns with regard to this Agency Letter, please contact Killian Swift by email at Swift.Killian@epa.gov 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,

for 

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

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Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

 Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82341-1	2. EPA Product Manager Demson Fuller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CleanBeyond Excel	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) IET, Inc. 4235 Commerce Street, Little River, SC 29566 <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.)

Notification of alternate brand name per PR Notice 98-10. Proposed alternate brand name: CleanBeyond Excel

Explanation continued on attached page.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
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	Metal Plastic Glass Paper Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per 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"/> Lithograph <input type="checkbox"/> Paper 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 Tim Shields	Title Director	Telephone No. (include Area Code) 843) 390-2500
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.		8. Date Application Received (Stamped)
2. Signature	3. Title Director	
4. Typed Name Tim Shields	5. Date	

NOTIFICATION

Date Revealed: _____
Reviewed By: _____

09-23-14
Miller Swift

CleanBeyond
Advanced Techniques in Healthy Cleaning
Excel

ACTIVE INGREDIENT:

Hypochlorous Acid..... 0.046%

OTHER INGREDIENTS: 99.954%

TOTAL: 100.000%

Contains 500 ppm Free Available Chlorine

STORAGE AND DISPOSAL

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

Storage: Store in a closed dark plastic container away from direct sunlight. Store container in a cool dry area. Product or urimates that cannot be used may be disposed in a sanitary sewer.

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

Container Disposal: Refillable container. Refill this container with same product only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refilled. Cleaning the container before final disposal is the responsibility of the person disposing the container. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for two minutes. Repeat this rinsing procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

Environmental Commitment

This product rapidly breaks down entirely to salt water. Not harmful to septic and sewer systems. This bottle is coded for recyclers. Check to see if recycling facilities accept colored HOPE. Contains no phosphorus, Socs, alcohol or phenols. Low Odor. Fresh and clean scent.



Aqueous Solution of Sodium Chloride

Active ingredient HOCl derived from naturally-occurring salt minerals and water.

A New Generation of Disinfectant

Cleans, Deodorizes, Disinfects, and Kills:

- Clostridium difficile (C diff) spores
- Mycobacterium bovis (Tuberculosis)
- Human Immunodeficiency Virus type 1 (HIV-1)
- Klebsiella pneumoniae New Delhi (NDM-1)
- Carbapenem Resistant
- Methicillin Resistant Staphylococcus aureus (MRSA)
- Vancomycin Resistant Enterococcus faecalis (VRE)

(See back panel for additional organisms)

This product meets AOAC efficacy testing standards for hospital disinfection. Meets requirements of OSHA's Bloodborne Pathogen Guidelines.

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS: 1 U.S. Gallon / 3.78 Liters

CleanBeyond Excel cleans and disinfects: hospitals, clinics, ambulances, emergency rooms, dentist's offices, home health care settings, retirement homes, correctional facilities, dormitories, schools, daycare centers, gymnasiums, locker rooms, hotels, cruise ships, airplanes, trains, theaters, stadiums, food processing plants, restaurants, bars, grocery stores, veterinary facilities, kennels, pet shops, office buildings, public facilities, and homes.

Do not use on steel, aluminum, silver, or chipped enamel. Prolonged contact with metal may cause pitting or discoloration. Test in an inconspicuous place for color washout or contact incompatibility.

Manufactured by:

I.E., Inc.
4235 Commerce St, Little River, SC 29566
(843) 390-2500 info@ietld.net

EPA Reg. No. 82341-1
EPA Est# 82341-SC-1

NSF Reg. No. 141871 and 142320
NSF Category Code D2 -
Antimicrobial agents not requiring a rinse

CleanBeyond Excel must be used within 30 days after being produced.

DATE PRODUCED:

FIRST AID

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center (PICNIC) 1-800-858-7378 for emergency medical treatment information.

DIRECTIONS FOR USE

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

DISINFECTION APPLICATIONS

Hard Non-Porous Surface Disinfection: To Clean, Disinfect and Deodorize Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply, Wipe, Spray or Dip CleanBeyond Excel at 500 ppm FAC to hard, non-porous surfaces with a cloth, wipe, mop or sponge. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. 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, 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.

Special Instructions for Cleaning Prior to Disinfection against Clostridium difficile endospores

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks, or eye covering.
Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with clean cloth, mop, and/or sponge saturated with product intended for disinfection. Cleaning should include vigorous wiping and/or scrubbing, until visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.
Infectious Materials Disposal: Cleaning materials used that may contain feces/wastes should be disposed of immediately in accordance with local regulations for infectious materials disposal.

For Killing Clostridium difficile spore: Clean hard, non-porous surfaces by removing gross filth, loose dirt, debris, blood/bodily fluids, etc. Apply this product and let stand for 10 minutes.

Special Instructions for Using this product to Clean and Decontaminate against HIV on Surfaces/Objects Soiled with Blood/Body Fluids

This product kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (e.g. hospitals, nursing homes) 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 Human Immunodeficiency Virus Type 1 (HIV-1) associated with AIDS.

Personal Protection: When handling items soiled with blood or body fluids, use appropriate barrier protection such as disposable latex gloves, gowns, masks, and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and other objects before applying this product.

Contact Time: Apply this product to area to be treated. Let stand for 10 minutes. Cleaning materials used that may contain feces/wastes should be disposed of immediately in accordance with local regulations for infectious materials disposal.

Disposal of Infectious Material: Blood And other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

Organism Table for Disinfection Applications

Bacteria
Clostridium difficile – spore (C. Diff) (ATCC 43598)
Escherichia coli (ATCC 11229)
Klebsiella pneumoniae New Delhi Metallo-Beta Lactamase (NDM-1) Carbapenem
Resistant, CDC 10002
Listeria monocytogenes (ATCC 7644)
Methicillin Resistant Staphylococcus aureus (MRSA) (ATCC 33591)
Pseudomonas aeruginosa (ATCC 15442)
Salmonella enterica (ATCC 10708)
Staphylococcus aureus (ATCC 6538)
Vancomycin Resistant Enterococcus faecalis (ATCC 51229) Mycobacterium
Mycobacterium bovis, BCG (Tuberculosis or TB)
Viruses Enveloped
Human Immunodeficiency Virus Type 1 (HIV-1), strain IIB (clade B), ZepionMetrix
Swine Flu Virus (H1N1) A/Swine/1976/31 (ATCC VR-99)
Food-Contact Surface Bacteria
Listeria monocytogenes (ATCC 7644)

SANITIZING APPLICATIONS

CleanBeyond Excel is an effective multi-purpose sanitizer that kills bacteria that may cause food poisoning. This product is acceptable as a sanitizer for all surfaces not always requiring a rinse in and around food processing areas.
Hard, Non-Porous Non-Food Contact Surfaces: To Sanitize Surfaces: For heavily soiled areas, a preliminary cleaning is required. Dilute 1:1.5 with Water to prepare a 200 ppm FAC solution. Use chlorine test strips to adjust to desired chlorine level. Apply sanitizing solution with cloth, mop, sponge, spray or immersion. Treated surfaces must remain wet for 2 minutes. Allow surfaces to air dry. This product kills 99.9% of bacteria on dirty surfaces in two minutes. To deodorize: Spray on surfaces as needed. **Hard, Non-Porous Food Contact Surfaces:** To Sanitize Surfaces: Wash, wipe, or rinse items with detergent and water, then apply 200 ppm sanitizing solution. Let stand 1 minute and wipe dry with clean towel or allow to air dry.

Organism Table for Sanitizing Applications

Non-Food Contact Surface Bacteria; Contact Time: 2 minutes
Barycenter erogenus (ACCT 13408)
Staphylococcus Aurellus (ACCT 6538)
Food-Contact Surface Bacteria; Contact Time: 60 seconds
Salmonella intricata (ACCT 6539)
Staphylococcus Aurellus (ACCT 6538)