

82341-1

3/4/2010

10413



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mr. Larry Jones
Integrated Environmental Technologies, Ltd.
4235 Commerce Street
Little River, SC 29566

MAR - 4 2010

Subject: EcaFlo Anolyte
EPA Registration No. 82341-1
Amendment Date: October 13, 2009
EPA Receipt Date: October 20, 2009

Dear Mr. Jones,

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) is acceptable with the conditions below.

Proposed Amendment

- Addition of microorganism

Conditions

Revise the label as follows:

- 1) Revise the cross contamination claims on page 3, 28th claim and page 4, 9th claim to read: "...cross contamination *between treated* hard non-porous surfaces..."
- 2) Revise Table Four, page 7 to include the following texts (two instances): "...Food contact surfaces must be rinsed with *potable water after application of disinfectant.*"
- 3) Make the following revisions to Table Five, page 8.
 - Delete the claims for "cooling towers" and "Lazy Rivers" as your label does not include directions for use at these sites.
 - Revise "pipeline" to state: "pipelines associated with oil and gas production."
 - Delete the claim for "Non-Food produce areas" as produce is food

4) Add the following text to the Container Disposal section: *“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 2 minutes. Dispose of rinsate as pesticide waste. 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.”*

Efficacy Data

The following efficacy study was submitted in support of this product. The review of this data is attached.

Study	MRID Number	Study Status
Swine Influenza virus H1N1 ATCC VR-99	478931-01	Acceptable, in the presence of 5% serum, 500 ppm free chlorine, 10 minute contact time.

General Comments

A stamped copy of the accepted labeling with conditions is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415 or Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: Stamped Label, DER DP 371839
7510P:T. Lantz:3/4/2010:82341-1 PRIA acceptable WC

EcaFlo® Anolyte

Aqueous Solution of Sodium Chloride

EcaFlo® solutions:

- are disinfecting solutions,
- are cost effective solutions to produce,
- are produced in a single stage process by a simple electrolytic cell,
- can be produced for use in medical, institutional, industrial and commercial applications,
- can be produced with a controlled pH and concentration of Free Available Chlorine (FAC), and
- are produced with low energy costs from water and salt.

ACTIVE INGREDIENT:

Hypochlorous Acid 0.046%

OTHER INGREDIENTS: 99.954%

TOTAL: 100.000%

Contains 500 ppm Free Available Chlorine (FAC)

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Manufactured by:
INTEGRATED ENVIRONMENTAL TECHNOLOGIES, LTD.
4235 Commerce St
Little River SC 29566
Ph: 843-390-2500 – Email: info@ietltd.net

EPA Reg# 82341-1

EPA Est# 82341-SC-1

EcaFlo® Anolyte must be used within 30 days after being produced. **DATE PRODUCED:** _____

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR - 4 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 82341-1

EcaFlo® Anolyte is an activated aqueous solution of sodium chloride produced by passing weak salt brine through an electrolytic cell and temporarily changing the properties of the salt water into a powerful oxidizing agent exhibiting antimicrobial properties. **EcaFlo® Anolyte** is produced at a near neutral 6.5 pH where the predominant antimicrobial agent is hypochlorous acid, an efficient and efficacious specie of chlorine. Hypochlorous acid kills bacteria.

The properties of **EcaFlo® Anolyte** can be precisely controlled by manipulating power to the electrolytic cell, brine flow rate through the cell and the conductivity of the brine in the cell. Anolyte can be applied as a liquid or spray.

EcaFlo® Anolyte freezes at 32° F and boils at 212° F. Anolyte is a colorless, aqueous solution, with a slight chlorine or ozone odor. After production, **EcaFlo® Anolyte** must be stored in a closed, plastic container in a cool, dark area away from direct sunlight. Anolyte is intended to be used soon after being produced. The Anolyte product must be used within 30 days of production.

DIRECTIONS FOR USE

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

OIL AND GAS APPLICATIONS

Frac Water – For typical water treatment, mix 5 US gallons of EcaFlo® Anolyte with 995 US gallons of frac water to 2.5 ppm FAC to mitigate and retard the growth of non-public health microorganisms such as anaerobic bacteria, aerobic bacteria and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Sour Wells - For typical well treatment, slug dose 168 US gallons at 500 ppm FAC of EcaFlo® Anolyte into the well bore on a daily or weekly basis to control unwanted non-public health microorganisms, reduce hydrogen sulfide gas and restore well integrity.

Produced Waters - For typical produced water treatment, mix 21 US gallons of EcaFlo® Anolyte with 979 US gallons of produced water to 10.5 ppm FAC to retard the growth of non-public health microorganisms.

Heater Treaters, Hydrocarbon Storage Facilities & Gas Storage Wells – For typical storage facility treatment, mix 126 gallons of EcaFlo® Anolyte at 500 ppm FAC into the water phase of the mixed hydrocarbon/water system to retard the growth of non-public health microorganisms, control 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 EcaFlo® Anolyte with 979 US gallons of injection water to 10.5 ppm FAC to retard the growth of non-public health microorganisms and control slime in pipelines.

Oil and Gas Transmission Lines - For typical transmission line treatment, slug dose 420 US gallons at 500 ppm FAC of EcaFlo® Anolyte into the transmission line on a daily or weekly basis to control unwanted non-public health microorganisms, such as SRB's, reduce microbiologically influenced corrosion (MIC) and remove the slime and associated sessile bacteria which can degrade pipeline integrity.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR - 4 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 82341-1

Hard, Non-Porous Surface Disinfection

To [Clean and] Disinfect [and Deodorize] Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply [Wipe or Dip] EcaFlo® Anolyte 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. Food contact surfaces such as counters and tables must be rinsed with potable water. Do not use on utensils, glasses or dishes.

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.

<u>Pathogen</u>	<u>Contact Time</u>
Salmonella enterica ATCC 10708	10 minutes
Pseudomonas aeruginosa ATCC 15442	10 minutes
Staphylococcus aureus ATCC 6538	10 minutes
Staphylococcus aureus MRSA ATCC 33591	10 minutes
Swine Influenza virus H1N1 ATCC VR-99)	10 minutes

Claims:

- + Broad spectrum disinfectant
- + One step cleaner/disinfectant
- + Aids in the reduction of cross-contamination between treated surfaces
- + Assures proper strength, product effectiveness and standardizes technique
- + Formulated for bacteria fighting
- + Bactericide – or – Bactericidal
- + Bathroom disinfectant
- + Kitchen disinfectant
- + Nursery disinfectant
- + Athletic facility disinfectant
- + Cleans and disinfects (insert use site(s) from tables 1-5)
- + Cleans and disinfects hard, non-porous surfaces
- + Cleans, deodorizes and disinfects
- + Deodorizes by killing the germs that cause odors
- + Disinfecting formula
- + Disinfects and deodorizes by killing bacteria and their odors
- + Disinfects hard, non-porous surfaces (throughout the (insert use site(s) from tables 1-5)
- + Easy and convenient disinfecting (throughout the (insert the use site(s) from tables 1-5)
- + Easy one-step cleaning and disinfecting
- + Effective against – or – Kills (insert any organism(s) from table above)
- + Effective against – or – Kills a wide range of bacteria including Staphylococcus aureus MRSA, Salmonella enterica, Pseudomonas aeruginosa
- + Effectively disinfects hard, non-porous, environmental surfaces
- + Eliminates odors at their source; bacteria
- + Eliminates - or – Reduces odors caused by bacteria
- + Fight(s) – and/or - Kill(s) – and/or – Effective against Salmonella enterica
- + Fight(s) – and/or - Kill(s) – and/or – Effective against Staphylococcus aureus MRSA
- + Fight(s) – and/or - Kill(s) – and/or – Effective against Pseudomonas aeruginosa .
- + Fight(s) – and/or – Stops – and/or – Prevent(s) cross-contamination on hard, non-porous surfaces (in your (list any use site))
- + Kills bacteria
- + Kills many common bacteria
- + Kills odor-causing bacteria
- + Kills – or – Effective against bacteria

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR - 4 2010

Under the Federal Insecticide,
Fungicide and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 82341-1

60013

- + Multi-purpose disinfectant
- + One-step cleaner and disinfectant
- + One-step disinfectant cleaner designed for general cleaning and disinfecting hard, non-porous environmental surfaces in health care facilities – or – (insert use site(s) from table 1)
- + Pseudomonocidal
- + Ready-to-use hospital disinfectant
- + Staphylocidal
- + The answer to your disinfecting needs
- + The quick – and/or – easy – and/or – convenient way to disinfect
- + This product controls cross-contamination on most hard, non-porous surfaces
- + This product meets AOAC efficacy testing requirements – or – standards for hospital disinfection
- + Use in public – or – common places where bacteria may be of concern on hard, non-porous surfaces
- + Use where control of the hazards of cross-contamination between treated surfaces is of Prime importance
- + Kills – or – Effective against H1N1 Swine Influenza virus

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAR -4 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 82341-1

GENERAL CLAIMS

- + Convenient
- + For general use
- + For use on nursery surfaces
- + Suitable for hospital use
- + Will not harm (insert surface material(s) from table 5)
- + Will not harm hard, non-porous inanimate environmental surfaces
- + Will not harm titanium-coated, medical grade stainless steel
- + Easy to handle
- + For use on bathroom surfaces
- + For use in athletic facilities
- + For use on athletic equipment

TABLE ONE: Medical:

USE SITES

- Ambulances – or – Emergency Medical Transport Vehicles
- Anesthesia Rooms – or – Areas
- Assisted Living – or – Full Care Nursing Homes
- CAT Laboratories
- Central Service Areas
- Central Supply Rooms – or – Areas
- Critical Care Units – or – CCUs
- Dialysis Clinics
- Emergency Rooms – or – ERs
- Health Care Settings – or Facilities
- Home Health Care Settings
- Hospitals
- Hospital Kitchens
- Intensive Care Units – or – ICUs
- Laboratories
- Medical Clinics
- Medical Facilities
- Medical – or – Physician’s – or - Doctor’s Offices
- Newborn – or – Neonatal Nurseries
- Nursing – or – Nurses’ Stations
- Orthopedics
- Outpatient Clinics
- Patient Restrooms
- Patient Rooms
- Pediatric Examination Rooms – or – Areas
- Pharmacies
- Physical Therapy Rooms – or – Areas
- Radiology – or – X-Ray Rooms – or – Areas
- Surgery Rooms – or – Operating Rooms – or – ORs

ACCEPTED
with COMMENTS
in EPA Letter Dated:

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 82341-1

SURFACES

- bed pans

exam - or - examination tables
 external surfaces of medical equipment - or - medical equipment surfaces
 external surfaces of ultrasound transducers
 gurneys
 hard, non-porous environmental hospital - or - medical surfaces
 hospital - or - patient bed railings - or - linings - or - frames
 IV poles
 Patient chairs
 Plastic mattress covers
 Reception counters - or - desks - or - areas
 Stretchers
 Wash basins
 Wheelchairs

TABLE TWO: Dental:

USE SITES

Dental Operatories
 Dental - or - Dentist's Offices

SURFACES

Dental countertops
 Dental operatory surfaces
 Dentist - or - dental chairs
 Hard, non-porous environmental dental surfaces
 Light lens covers
 Reception counters - or - desks - or - areas

**ACCEPTED
 with COMMENTS
 in EPA Letter Dated:**
 MAR 24 1991
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 8234-1

TABLE THREE: Veterinary:

Animal Premises: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap and/or detergent and rinse with water. Apply EcaFlo® Anolyte at 500 ppm FAC. Saturate surfaces with solution for 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. After application, ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

USE SITES

Animal Housing Facilities
 Animal Life Science Laboratories
 Animal - or - Pet Grooming Facilities
 Kennels
 Livestock - and/or - Swine - and/or - Poultry Facilities

Pet Areas
 Pet Shops – or – Stores
 Small Animal Facilities
 Veterinary Clinics – or – Facilities
 Veterinary Offices
 Veterinary – or – Animal Hospitals

SURFACES

Animal equipment automatic feeders
 Cages
 External surfaces of veterinary equipment
 Feed racks
 Fountains
 Hard, non-porous environmental veterinary surfaces
 Pens
 Reception counters – or – desks – or – areas
 Stalls
 Troughs
 Veterinary care surfaces
 Watering appliances

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 82344-1

TABLE FOUR: Food Service:

Food Processing and Service Establishments: Before using this product, food products and packaging materials must be removed from the area or carefully protected.

USE SITES (Food contact surfaces must be rinsed with clean, potable water)

Bars
 Cafeterias
 Commercial – or – Institutional Kitchens
 Delis
 Fast Food Chains – or – Restaurants
 Food Preparation and Processing Areas
 Food Processing and Fabrication Areas
 Food Service – or – Processing Establishments
 Food Serving Areas
 Other Food Service Establishments
 Restaurants
 School Kitchens

SURFACES (Food contact surfaces must be rinsed with clean, potable water)

Surfaces where disinfection is required
 Exterior surfaces of Appliances
 Exterior surfaces of Dish racks
 Drain boards
 Exterior surfaces of Food Cases
 Exterior surfaces of Food Trays

- Exterior surfaces of Freezers
- Hoods
- Exterior surfaces of Microwaves
- Outdoor furniture (excluding wood frames and upholstery)
- Exterior surfaces of Ovens
- Exterior surfaces of Refrigerators
- Salad bar sneeze guards
- Exterior surfaces of Stoves – or – Stovetops

TABLE FIVE: Miscellaneous/General:

USE SITES

- Airplanes
- Blood Banks
- Boats
- Bowling Alleys
- Butcher Shops
- Chillers
- Churches
- Colleges
- ~~Cooling Towers~~
- Correctional Facilities
- Cruise Lines
- Day Care Centers
- Dormitories
- Factories
- Funeral Homes
- Grocery Stores
- Gymnasiums – or – Gyms
- Health Club Facilities
- Hotels
- Industrial Facilities
- Laundromats
- Laundry Rooms
- ~~Lamp Poles~~
- Locker Rooms
- Manufacturing Plants – or – Facilities
- Military Installations
- Motels
- Pipelines
- Preschool Facilities
- ~~Non-food Produce Areas~~
- Public Areas
- Recreational Centers – or – Facilities
- Restrooms – or – Restroom Areas
- School Buses
- Schools

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAY - 4 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 8234/-1

Shelters
 Shower Rooms
 Storage Rooms – or – Areas
 Supermarkets
 Trains
 Universities
 Wineries
 Yachts

SURFACE

Bathroom fixtures
 Bath tubs
 Behind and under counters
 Behind and under sinks
 Booster chairs
 Cabinets
 Ceilings
 Cell(ular) – or – wireless – or – mobile – or – digital phones
 Chairs
 Computer keyboards
 Computer monitors
 Counters – or – countertops
 Cribs
 Desks
 Diaper – or – infant changing tables
 Diaper pails
 Dictating equipment surfaces
 Doorknobs
 Exterior – or – external toilet surfaces
 Exterior – or – external urinal surfaces
 Faucets
 Floors
 Garbage – or – trash cans
 Grocery store – or – supermarket carts
 Hampers
 Hand railings
 Headsets
 Highchairs
 Lamps
 Linoleum
 Other telecommunications equipment surfaces
 Playpens
 Shelves
 Showers – or – shower stalls
 Sinks
 Stall doors
 Tables
 Telephones
 Tiled walls

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:
 JAN - 4 2010
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 82341-1

- Toilet rims
- Toilet seats
- Towel dispensers
- Toys
- Vanity tops – or – vanities

SURFACE MATERIALS

- Baked enamel
- Chrome
- Common hard, non-porous household – or – environmental surfaces
- Formica
- Glass
- Glazed ceramic tile
- Glazed porcelain
- Laminated surfaces
- Plastic laminate
- Glazed porcelain enamel
- Stainless steel
- Synthetic marble
- Vinyl tile
- Similar hard, non-porous surfaces except those excluded by the label

Not Recommended For Use On – or – Avoid Contact With:

- Aluminum
- Brass
- Chipped enamel
- Clear plastic
- Clothes
- Copper
- Fabrics
- Gold
- Natural marble
- Painted surfaces
- Paper surfaces
- Natural rubber
- Sealed granite
- Silver
- Unfinished wood
- Wood

ACCEPTED
with COMMENTS
in EPA Letter Dated:
 (MAR - 4 200)

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 82341-1

130813

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.

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

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 (NPIC) 1-800-858-7378 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
CAUTION

ACCEPTED
with COMMENTS
in EPA Letter Dated
[Signature]

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 82341-1