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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MAY 5 2009

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

Subject: EcaFlo Anolyte
EPA Registration No.: 82341-1
Amendment Date: November 17, 2008
EPA Receipt Date: December 4, 2008

Dear Mr. Jones,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with conditions.

Proposed Amendment

Adding an organism, MRSA

Conditions

Revise the label as follows:

1) Any product label that states or implies the use of a product as a general disinfectant on medical devices or medical equipment surfaces must have PR Notice 94-4 MOU language. Add the following statements to the "Hard, Non-Porous Surface Disinfection" section of the label:

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 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 of high-level disinfection.

2) Revise the "Pesticide Disposal" and "Container Disposal" statements on page 10 to be in agreement with PR Notice 2007-4 by stating the following:

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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: Nonrefillable Container. Do not refill or reuse container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

3) The "Precautionary Statements" for eye irritation on page 11 is incomplete and not in agreement with the Label Manual. Revise to state "Causes moderate eye irritation. Avoid contact with eye. Wear safety glasses or goggles. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Data Summary

Data Requirement	Means of Support	Status
AOAC Use Dilution Test - MRSA	Submitted study, MRID 47617201	Acceptable

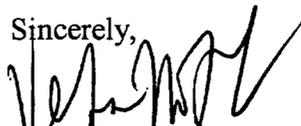
General Comments

A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies 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) 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 or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

 Welma Noble
 Product Manager (31)

Regulatory Management Branch I
 CONCURRENCES
 Antimicrobials Division (7510P)

SYMBOL	SURNAME	DATE					

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:	<u>99.954%</u>	
	TOTAL:	100.000%

Contains 500 ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN
CAUTION
 See Back Panel for Precautionary Statements

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

RECORDED
 with COMMENTS
 in EPA Files Dated:
MAY 5 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947, and the amendments thereto, this pesticide is registered under EPA Reg. No. 82341-1

EPA Reg# 82341-1

EPA Est# 82341-SC-1

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

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.

DISINFECTION APPLICATIONS

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.

<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

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
- + 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

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

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

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

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
- Lazy Rivers
- 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

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

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

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.

Disposal: Triple rinse container, then offer for recycling, refilling or reconditioning. Empty container may be reused. Place in trash or offer for recycling if available.

Wood

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.

Disposal: Triple rinse container, then offer for recycling, refilling or reconditioning. Empty container may be reused. Place in trash or offer for recycling if available.

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.

If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Causes eye irritation. Avoid contact with eyes.