

86854-1

2/2/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

FEB - 2 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Robert Brennis
Brennis Consulting Services, Inc.
6628 Birchleigh Way
Alexandria, VA 22315

FILE COPY

Subject: Clarentis LLC
Ultra-Lyte
EPA Reg. No.: 86854-1
Application Dated: January 5, 2011
Receipt Dated: January 6, 2011

Dear Mr. Brennis:

The labeling for the product referred to above submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with conditions.

Proposed Amendment

•To remove the restriction for generation of Ultra-Lyte on site.

Conditions

1. Revise the Precautionary statement to read "Cause moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear and goggles when dispensing and using this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse."

2. Products that imply use as a general disinfectant on medical devices or medical equipment surfaces must include the PR Notice 94-4 language below and be qualified with a double asterisk, which connects it to the use site on the label for this product.

****This product is not to be used as a terminal sterilant/high level disinfectant on any surface of 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 bold 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 of high level disinfection.**

General Comments:

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

Should you have any questions or comments concerning this letter, please contact me at Henson.Wanda@epa.gov or call (703) 308-6345.

Sincerely,



Wanda Y. Henson
Acting Product Manager – Team 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

3/13

ACCEPTED
with COMMENTS
EPA Letter Dated:
FEB - 2 2011

Ultra-Lyte™ Under the Federal Insecticide, Fungicide and Rodenticide Act as amended for use as a disinfectant, registered under EPA Reg. No. 86854-1

Aqueous Solution of Sodium Chloride

Ultra-Lyte™ solutions:

- are disinfecting solutions,
- are cost-effective solutions to produce,
- are produced in a simple process by an 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
See Back Panel for Precautionary Statements

Manufactured by:
 Clarentis LLC
 191 NE Boad Haven Road
 Belfair, WA 98528
 Ph: 866-363-7930 Email: info@ultra-lyte.com

EPA Reg. # 086854-1

EPA Est. # 086854-WA-001

Ultra-Lyte™ must be used within 30 days after being produced. Store in a cool area and do not break the seal on the bottle until ready for use.

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 (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 moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Physical or Chemical hazards

Ultra-Lyte is not compatible with other chemicals such as acids and hydrogen peroxide.

Ultra-Lyte™ 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. **Ultra-Lyte™** 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 **Ultra-Lyte™** 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. **Ultra-Lyte™** can be applied as a liquid or spray.

Ultra-Lyte™ freezes at 32° F and boils at 212° F. The anolyte is a colorless, aqueous solution, with a slight chlorine or ozone odor. After production, **Ultra-Lyte™** must be stored in a closed, plastic container in a cool, dark area away from direct sunlight. The Ultra-Lyte product must be used within 30 days of production.

*Salmonella Enterica, Staphylococcus aureus, Staphylococcus aureus MRSA, Escherichia-Coli O157:H7, Listeria Monocytogenes, Pseudomonas aeruginosa.

DISINFECTION APPLICATIONS

DIRECTIONS FOR USE

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

Hard, Non-Porous Surface Disinfection

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 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

To [Clean and] Disinfect [and Deodorize] Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply [*Wipe, Spray or Dip*] **Ultra-Lyte™ at 500 ppm FAC** (full strength) 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
Staphylococcus aureus ATCC 6538	10 minutes
Staphylococcus aureus MRSA ATCC 33591	10 minutes
Swine Influenza virus (H1N1) ATCC VR 99	10 minutes
Escherichia-Coli O157: H7 ATCC 35150	10 minutes
Listeria Monocytogenes ATCC 19111	10 minutes
Pseudomonas aeruginosa	10 minutes

Claims:

- + 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 + 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, Escherichia-Coli O157:H7, Listeria Monocytogenes
- + 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 – Kill(s) – and/or – Effective against Escherichia-Coli O157:H7
- + Fight(s) – and/or – Kill(s) – and/or – Effective against Listeria Monocytogenes
- + Fight(s) – and/or – Kill(s) – and/or – Effective against Swine Influenza virus (H1N1)
- + Fight(s) – and/or – Stops – and/or – Prevent(s) cross-contamination between treated 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 disinfection needs
- + The quick-and/or easy and/or –convenient way to disinfect
- + This product controls cross-contamination between treated 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
- + Easy to handle
- + For general use
- + For use on bathroom surfaces
- + For use on nursery surfaces
- + For use in athletic facilities
- + Suitable for hospital use

- + For use on athletic equipment
- + 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

Medical Uses

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

Bedpans
 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

Dental Uses

USE SITES:
Dental Operatories
Dentist – 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

Veterinary Uses

USE SITES
Animal Housing Facilities
Animal Life Science Laboratories
Animal - or -Pet Grooming Facilities
Kennels
Lab Animal Facilities
Livestock – and/or- Poultry Facilities
Pet Areas
Pet Shops – or- Stores
Small Animal Facilities
Veterinary Clinics - or -Facilities
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

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 Ultra-Lyte™ (full strength) 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.

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 potable water after application of disinfectant)

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 potable water after application of disinfectant)

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

Miscellaneous / General Uses

USE SITES

- Airplanes
- Blood Banks
- Boats
- Bowling Alleys
- Butcher Shops
- Chillers
- Churches
- Colleges
- 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
- Locker Rooms
- Manufacturing Plants - or - Facilities
- Military Installations
- Motels
- Naval facilities
- Oil and gas applications
- Oil platforms
- Pipelines associated with oil & gas production
- Preschool Facilities
- Public Areas
- Public Transportation
- Recreational Centers - or - Facilities
- Restrooms - or - Restroom Areas
- School Buses
- Schools
- Shelters
- Ships
- Shipyards
- Shower Rooms
- Storage Rooms - or - Areas
- Supermarkets
- Trains
- Universities
- Wineries
- Yachts
- 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
Home Health Care Settings
Hospital Kitchens
Intensive Care Units – or – ICUs
Laboratories
Physician's – or – Doctor's Offices
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Plastic mattress covers
Reception counters - or - desks - or - areas
Wash basins
Wheelchairs
Dental - or - Dentist's Offices

SURFACE

Bathroom fixtures
Bath tubs
Behind and under counters
Behind and under sinks
Booster chairs
Cabinets
Ceilings
Ceiling Fans
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
- Glazed ceramic tile
- Laminated surfaces
- Plastic laminate
- Glazed porcelain enamel
- Stainless steel
- Synthetic marble
- Vinyl tile
- Dental countertops
- Dentist - or - dental chairs
- Hard, non-porous environmental dental surfaces
- Light lens covers
- Reception counters - or desks - or areas.

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

OIL AND GAS APPLICATIONS – Non-Public Health

Frac Water – For typical water treatment, mix 5 US gallons of Ultra-Lyte™ 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 Ultra-Lyte™ 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 Ultra-Lyte™ 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 Ultra-Lyte™ 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 Ultra-Lyte™ 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 Ultra-Lyte™ 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.

PESTICIDE STORAGE AND DISPOSAL

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

Pesticide 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: Non-refillable Container. Do not refill or reuse container. Triple rinse container after emptying. 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.