



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 29, 2015

Kevin Kutcel  
KRK Consulting LLC  
Agent for Clarentis Technologies, LLC  
5807 Churchill Way  
Medina, OH 44256

Subject: Label Amendment – addition of language for product to be used within 30 days or be tested with test kit and addition of non-public health claims  
Product Name: Ultra-Lyte  
EPA Registration Number: 86854-1  
Application Date: March 6, 2015  
Decision Number: 502778

Dear Kevin:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Ben Chambliss by phone at (703) 308-8174, or via email at [chambliss.ben@epa.gov](mailto:chambliss.ben@epa.gov).

Sincerely,

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

Demson Fuller, Product Manager 32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: stamped label

**A C C E P T E D**

**06/29/2015**

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 86854-1

## Ultra-Lyte®

### 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 Technologies, LLC

22 St. James Drive, Palm Beach Gardens, FL 33418

Tel: (561) 799-9299, info@clarentis.com

EPA Reg. # 86854-1

EPA Est. # 86854-FL-001

Ultra-Lyte® must be used within 30 days after being produced *OR product must be tested with chlorine test kit provided by Clarentis Technologies, LLC. DO NOT USE PRODUCT when Chlorine concentration is below 450ppm.*

Store in a cool area and do not break the seal on the bottle until ready for use.

**Date produced:**

\*\*This product is not meant 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 bold barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

<b>FIRST AID</b>	
<b>If in Eyes</b>	Hold eye open and rinse slowly and gently with water for 15-20 minutes for 15-20 minutes. Remove contact lenses, if present after the first 5 minutes, then continue rinsing eye.
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**

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear and goggles when dispensing or 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.

**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**

**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
- + Inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, mildewstatic (mold and mildew), and algae.
- + 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 operator 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.

### 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 rinse at 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.