

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 30, 2023

Kresti A. Lyddon Agent for, LuminOre Copper Touch

Electronic Transmittal: [klyddon@lewisharrison.com]

Subject: Label Amendment – To Add Several "Me-Too" Uses to the Product Label

Product Name: LuminOre CopperTouch Antimicrobial Surfaces

EPA Registration Number: 89266-1 Received Date: February 24, 2023 Action Case Number: 00438132

Dear Ms. Lyddon:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 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. Pursuant to 40 CFR 156.10(a)(6) 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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

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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 Karen Leavy by phone at (202)-566-0668, or via email at Leavy.Karen@epa.gov.

Sincerely,

Tara Flint Silva, Acting Product Manager 31

Regulatory Management Branch I

Antimicrobials Division

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Office of Pesticide Programs

Enclosure: stamped label

Master Label Containing

Sublabel 1. Complete Label Sublabel 2. Hang Tag Label

Sublabel 1. Complete Label

LuminOre Copper Touch Antimicrobial Surfaces Antimicrobial Copper Surface Active Product

ACTIVE INGREDIENT:

*Contains 3.8 oz. of copper per ft²

EPA Reg. No.: 89266-1

EPA Est. No.: XXXXX-XX-XXX

Net Wt.: XX

LuminOre, Incorporated 6060 Corte del Cedro Carlsbad, CA 92011 ACCEPTED

08/30/2023

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

89266-1

DIRECTIONS FOR USE

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

(Note: The surface of this product contains copper, which functions as an antimicrobial agent. Product types that can be sold pursuant to this label are listed below. None of these product types are approved for direct food contact or food packaging uses).

Touch Surface Components

Healthcare Facilities

- Bedrails, footboards
- Toilet seats
- Flush handles
- Over-bed tables
- Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)
- o Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- Bedrails, assistance rails,
- Toilet safety rails
- Carts

Hospital carts (table surfaces, handles, legs)

Computer carts

Record carts

Phlebotomy carts

Other Carts (tables/surfaces, shelving, railings, handles, pulls)

- Equipment carts (horizontal surfaces, frames, handles)
- o Door push plates, kick plates, mop plates, stretcher plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Alcohol sanitizer dispenser, handle
- o Paper towel holders, facial tissue holders, toilet paper holders
- o Air hand dryer, controls and push buttons on air hand dryers
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surfaces)
- o Grab bars in bathrooms showers and bathtubs
- o Panic bars on emergency room doors
- Towel bars
- Countertops and tabletops (non-food use only)
- o Door pulls,
- Toilet and urinal hardware, levers, push buttons
- Closures
- Vertical locking arms
- o Vertical cover guards
- Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames
- Telephone handsets and surfaces (housings), keypad

- Kitchen surfaces, non-food contact only: table tops, cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles
- Wall tiles
- Instrument handles

Medical equipment knobs, pulls and handles for:

- Drug delivery systems
- Monitoring systems
- Hospital beds
- Office equipment
- Operating room equipment
- Stands and fixtures

Types of knobs: e.g., Prong, fluted, push/pull, T-handle, tapered, and ball knobs

- o Intravenous (IV) poles, bases, hangers, clips
- o Trays, instruments, non-food contact
- o Pans (bed)
- Walkers, wheelchair handles, and tubular components
- o Computer keyboards: keys, housings, computer mouse surfaces
- Exercise and rehabilitation equipment, handles, bars
- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- o Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Lighting products: X-ray illuminators, operating rooms, patient examination rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges)
- Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV poles
- Critical care cart: Table top, drawer, drawer pull,
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- Grab handles on privacy curtains
- o Lids of laundry hampers, trash canisters, and other containers
- Electrical wallplates

Community Facilities (including various public and commercial buildings)

- o Shopping cart handles, child seats, handrails
- Toilet seats
- Flush handles
- o Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- o Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- o Soap dispenser (wall mounted): push bar and dispenser itself
- o Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Light switches, switch plates

- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- Signage
- Vending machines, non-food contact only
- Window sills
- Electrical wallplates

Residential Buildings (including homes, apartments, apartment buildings and other residences)

- Kitchen surfaces, non-food contact only: table tops, handles, cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Toilet seats
- Flush handles
- Bedrails, footboards
- Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- o Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Countertops and tabletops (non-food use only)
- Door pulls
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Light switches, switch plates
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Wall tiles
- o Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Television control knobs and buttons
- o Lids of laundry hampers, trash canisters, and other containers
- o Television remote
- Magazine rack
- Radiator cover
- o Window sills
- Electrical wallplates
- o Baby cribs: rails, fittings, brackets, supports
- Bowl stands
- Monitor (television, computer, etc.) housing

Mass Transit Facilities

- Handrails
- o Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- Grab bars and handles
- Tiles: wall, floor
- o Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- Signage
- Vending machines, non-food contact only

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring
- Chapel pews

Airplane Interior Surfaces

- o Seats
- Seat belt buckles
- Stow bin
- Latches
- Door handles
- Lavatory
- Galley carts, non-food contact
- Sidewalls
- o Tray Tables, non-food contact
- Cargo holds

Space Vehicle Interior Surfaces

- Seats, sidewalls
- Galley, non-food contact
- Exercise Equipment
- Payload racks
- Waste hygiene areas

Planetary Habitat Interior Surfaces

- Sidewalls
- Airlock touch surfaces
- o Seats
- Galley, non-food contact
- Waste hygiene areas
- Latches
- Door handles
- Sleep quarters
- Equipment storage containers

STORAGE AND DISPOSAL

Storage: Storage areas must be locked and secure from vandalism, with precautionary signs posted.

Disposal: Dispose of by recycling or put in trash.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

Sublabel 2. Hang Tag Label

(Note: The product types listed above may be sold and distributed under EPA Registration Number 89266-1. These products must bear the label below, with one or more of the listed claims. FRONT PANEL

LuminOre Copper Touch Antimicrobial Surfaces

Active Ingredient:

 Copper*
 85.0%

 Other
 15.0%

 [Total
 100.0%]

See [Back/Side Panel][Insert] for Directions for Use

NET WEIGHT: lbs [brand name]

*Contains 3.8 oz. of copper per ft2

BACK/INSERTPANEL

LuminOre Copper Touch Antimicrobial Surfaces

Laboratory testing has shown that when cleaned regularly this surface:

- Continuously reduces bacterial* contamination, achieving 99.9% reduction within 2 hours of exposure.
- Kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within 2 hours of exposure.
- Delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours.
- Kills greater than 99.9% of bacteria* within 2 hours and continues to kill 99% of bacteria* even after repeated contaminations.
- Helps inhibit the buildup and growth of bacteria* within 2 hours of exposure between routine cleaning and sanitizing steps.
- This product continuously kills bacteria left behind [by dirty hands][on the surface] killing more than 99.9% of bacteria within 2 hours.
- * Staphylococcus aureus, Enterobacter aerogenes, Methicillin-Resistant Staphylococcus aureus (MRSA), Escherichia coli O157:H7 and Pseudomonas aeruginosa

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. *Proper Care and Use. (The following paragraph should appear on items intended to be used in health care facilities*)Clean and sanitize according to standard practice. Healthcare facilities must maintain the product in accordance with infection control guidelines. The use of this surface is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. This surface has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.

This surface may be subject to recontamination and the level of active bacteria at any time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order to have proper antimicrobial effect, this product must be cleaned and maintained according to the directions for use.

Do not wax, paint, lacquer, varnish, or otherwise coat this product.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of this surface. Cleaning agents typically used for traditional hard, non-porous touch surfaces are permissible. The appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. Normal tarnishing or wear of this surface will not impair antibacterial effectiveness.

Not approved for direct food contact or food packaging uses.

[Items exposed to outdoor environmental conditions are not representative of indoor laboratory test conditions, and, therefore, may impart reduced efficacy if not cleaned when visibly soiled.]

STORAGE AND DISPOSAL

Storage: Storage areas must be locked and secure from vandalism, with precautionary signs posted.

Disposal: Dispose of by recycling or put in trash.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

EPA Reg. No. 89266-1 EPA Est. No. XXXX-

Manufactured by:

LuminOre, Incorporated, 6060 Corte del Cedro, Carlsbad, CA 92011