

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 2, 2022

Abigail T.D. Wacek Senior Regulatory Consultant Revere Copper Products, Inc. Electronic Transmittal: abigail.wacek@tsgconsulting.com

Subject: Label Amendment – Remove viral claims from label Product Name: Revere Antimicrobial Copper EPA Registration Number: 85341-3 Received Date: May 23, 2022 Action Case Number/Decision Number: 00365265

Dear Abigail T.D. Wacek:

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. You must cease distribution or sale of products with labeling bearing the residual viral claims; any new product manufactured after the date you received EPA's May 18, 2022 letter, which is the date that label amendment for residual virucidal claims expired, must bear this new labeling or subsequently approved 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), products that have already been released for shipment or are in the channels of trade may continue to be distributed or sold under previously approved labeling for a period of 18 months after the expiration of the label amendment for residual virucidal claims. "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, you may contact Joe Daniels via email at daniels.joseph@epa.gov.

Sincerely,

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John Hebert, Chief Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure: Stamped Label



Revere Antimicrobial Copper™ AND ASSOCIATED FABRICATED PRODUCTS MASTER LABEL

The Master Label consists of the label that will accompany the Revere Antimicrobial CopperTM Antimicrobial Alloys and a label that will accompany each product fabricated using a registered Revere Antimicrobial CopperTM alloy.

[Alloy Label – Front Panel]

Revere Antimicrobial Copper[™] AND ASSOCIATED FABRICATED PRODUCTS

Active Ingredient: Copper Other 96.2% Total 100%
ACCEPTED 06/02/2022 Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 85341-3

EPA Registration No. 85341-3 EPA Establishment No. 85341-NY-001 Made in the United States by: Revere Copper Products, Inc. One Revere Park Rome, New York 13440

Net Weight: XXX lbs XXX ounces of Revere Antimicrobial Copper™

DIRECTIONS FOR USE

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

Revere Antimicrobial CopperTM Antimicrobial Copper Alloys

These alloys are only intended for the manufacture and fabrication of touch surface components for use in hospitals, healthcare facilities, laboratories, and various public, commercial, and residential buildings. [The claims listed on the attached fabricated product label may be made in connection with the marketing and sale of Revere Antimicrobial Copper[™] Antimicrobial Copper Alloys and fabricated products made from Revere Antimicrobial Copper[™] Antimicrobial Copper Alloys under EPA Registration Number 85341-3.

A list of components that may be fabricated out of Revere Antimicrobial CopperTM Antimicrobial Copper Alloys is specified below. Revere Antimicrobial CopperTM Antimicrobial Copper Alloys are not approved for direct food contact or food packaging uses.

Touch Surface Components

Healthcare Facilities

- o Bedrails, footboards
- 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
- o Bedrails, assistance rails,
- Toilet safety rails
- o 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
- Water fountains: bubbler head, drain strainer, handle
- Alcohol sanitizer dispenser, handle
- o Paper towel holders, facial tissue holders, toilet paper holders
- 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
- Panic bars on emergency room doors

- Towel bars
- o Showerheads
- o Countertops and tabletops (non-food use only)
- o Hinges, locks, latches, and trim
- o Door stops, door pulls, and protector guards
- o Toilet and urinal hardware, levers, push buttons
- o Toilet seat inlay for lifting of seat
- o Closures
- o Vertical locking arms
- o Vertical cover guards
- Protection bars
- o Light switches, switch plates
- o Visitor chairs: armrests, metal frames
- Thermostat covers, control knobs and wheels
- o Telephone handsets and surfaces (housings), keypad
- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles (non-porous)
- Ceiling tiles (non-porous)
- Wall tiles (non-porous)
- o 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, knurled, push/pull, T-handle, tapered, and ball knobs

- o Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- o Pans (bed)
- o Walkers, wheelchair handles, and tubular components
- o Computer keyboards: keys, housings, computer mouse surfaces
- o 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, lock, copper wire baskets for storage of equipment and charts.
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- o Medical records: Chart holders, clipboards, filing systems
- o Storage Shelving: wire shelving etc. for medical supplies
- Grab handles on privacy curtains
- o Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television controls: knobs, buttons, remote
- o Monitor (television, computer, etc.) housing
- o Cup Holder
- o Toothbrush holder
- Soap holder, dispenser
- o Magazine rack
- o Signage
- o Coat rack and hooks
- o Shower curtain rings
- o Radiator cover
- o Bracelets
- o Pens
- Badge clips
- o Name tags
- o Patient gown snaps
- Window sills, pulls and locks
- Electrical wallplates
- o Medical equipment washers: exterior surfaces, housing, handles, pulls

Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- o ATM machines: keys, housing
- o Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- o Exercise equipment, handles, bars
- o 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)
- o Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- o Casement (cranks, levers, hinges)

- Single and double-hung windows (locks and pulls)
- Light switches, switch plates
- o Lids of laundry hampers, trash canisters, and other containers
- o Magazine rack
- o Signage
- o Coat rack and hooks
- Shower curtain rings
- Radiator cover
- o Bracelets
- o Badge clips
- o Name tags
- Vending machines (non-food contact only)
- o Window sills
- o Electrical wallplates
- o Clip boards
- o Office supplies: paper clips, staplers, tape dispensers
- o Gym/Health Club: locker room seats, benches
- o Water fountains: knobs, buttons, handles, drains, push bar, basin
- Restrooms: toilet flush valves, flush buttons, faucet handles, hand dryer activation buttons, soap dispenser push bar/button

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

- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- o Bedrails, footboards
- o Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- o Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- o Grab bars in bathrooms showers and bathtubs
- o Towel bars
- o Showerheads
- Countertops and tabletops
- o Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- o Toilet and urinal hardware, levers, push buttons
- o Toilet seat inlay for lifting of seat
- o Light switches, switch plates
- o Thermostat covers, control knobs and wheels
- o Telephone handsets and surfaces (housings), keypad
- Floor tiles (non-porous)
- Ceiling tiles (non-porous)

- Wall tiles (non-porous)
- o Computer keyboards: keys, housings, computer mouse surfaces
- o Exercise equipment, handles, bars
- o Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- o Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- o Television control knobs and buttons
- o Lids of laundry hampers, trash canisters, and other containers
- o Bedside pitchers
- Closet rods and hangers
- o Television remote
- o Cup Holder
- Toothbrush holder
- Soap holder, dispenser
- o Magazine rack
- o Coat rack and hooks
- o Shower curtain rings
- o Radiator cover
- o Window sills
- o Electrical wallplates
- o Baby cribs: rails, fittings, brackets, supports
- o Bowl stands
- o Office supplies: paper clips, staplers, tape dispensers
- o Monitor (television, computer, etc.) housing

Mass Transit Facilities

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

Laboratories

- Incubator interior and outside surfaces, including culture chambers, walls, shelving and support brackets, handles, circulating fan assemblies, pan
- Laboratory surfaces: table tops, counter tops, handles, cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs
- Laboratory carts, trays, and pans
- o Door handles, knobs, latches and locks

o Laboratory equipment: safety cabinets, enclosures, vent hoods

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring
- Chapel pews
- Eye glass frames and protective eye wear
- o Pens
- o Combs
- o Ashtrays
- o Massager, hand-held: handle, buttons, knobs
- Push/pull device
- Smartphone and tablet covers and cases
- Stylus for touch screens
- Personal headphone touch surfaces
- Hand-held door opening device
- o Bottle openers

Do not wax, paint, lacquer, varnish, or otherwise coat touch surfaces.

STORAGE AND DISPOSAL

Dispose of excess by recycling.

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.

Revere Antimicrobial CopperTM Fabricated Product Label

FRONT

[This (touch surface) (product)] made from **Revere Antimicrobial CopperTM**

BACK

Revere Antimicrobial Copper™

- Laboratory testing has shown that when cleaned regularly this surface:
- Continuously reduces bacteria* 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 two 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/component name] is made (out of)(from) a (copper)(touch) surface that 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, Pseudomonas aeruginosa and, Vancomycin – Resistant Enterococcus faecalis (VRE).

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. 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

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. 85341-3 EPA Est. No. . [Product Manufacturer Number]- 85341-NY-001 Manufactured by: [Product Manufacturer Company Name and Address] Revere Copper Products, Inc. One Revere Park Rome, New York 13440