

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

SEP 1 3 2012

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mr. T. O'Shaughnessy President for, Revere Copper Products, Inc. One Revere Park Rome, NY 13440

Mail to: Mr. Micah T. Reynolds 1150 18th Street, NW, Suite 1000 Washington, D.C. 20036

Subject: Revere Antimicrobial Copper
EPA Registration Number 85341-1
Your Notification Dated August 15, 2012
EPA Received Date August 17, 2012

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add marketing logo to the product labeling, is acceptable.

The notification has been made part of the permanent file.

If you have questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,

Marshall Swindel

Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7510P)

Form Approved. Oh. No. 2070-0060. Approval expires 05-31-98

Please read instructions on reverse side before completing orm

≎EPA	United States Environmental Protection Washington, DC 20460				gency ☐ Regist ☐ Amend				OPP Identifier Number			
			Applicati	on for F	Pesticide – Sec				<u> </u>			
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5. Name And Addres	s Of Ar	pplicant (Include ZIP Co	ode)		6. Expedited Re							
Revere Copp		roducts, Inc.		1	(b)(i), my product							
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Rome, NY 13	440			,							_	
Check	cif this i	is a new address			Product Name _							
				Sec	ction II						·	
Amendment – Explain below. Resubmission in response to Agency letter dated Notification – Explain below.				Final Printed labels in response to Agency letter dated "Me Too" Application. Other – Explain Below.								
This notification is co labeling or the confid to EPA. I further und of FIFRA and I may t	onsisten dential si derstand be subje	Notification to ad the with the provisions of statement of formula of the did that if this notification is ect to enforcement action pt with Micah Rey	PR Notice 98- this product. I is not consiste on and penaltie	-10 and EPA I understand ent with the t es under se	d that it is a violation terms of PR Notice 9 ections 12 and 14 of F	of 18 U.S. 98-10 and FIFRA.	.C. Sec. 40 CFR	1001 to wil R 152.46, thi	Ifully make a is product ma	any false sta ay be in viol	atement plation	
				Sec	ction III							
1. Material This Prod	uct Will	Be Packaged In:										
Child Resistant Pack Yes* No					Water Soluble Packaging Yes No			2. Type of Container Metal Plastic				
* Certification n be submitted	านst	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Unit Pa	ackaging wgt. Container Paper				(Specify)			
3. Location of Net Contents Information 4. Size(S) R Label Container			4. Size(S) Re	etail Container 5. L			Location of Label Directions On Label On Labeling accompanying product					
6. Manner in Which L	abel is	Affixed to Product	Lithogram Pager gl Stenciled	lued		Other			Nes-			
					tion IV				-			
	mplete i	items directly below for	identification (I to be contacted, if n	iecessary,	, to proce			ecc 2-1		
Name Micah T. Reynolds	, Tech	nology Sciences Gro	oup, Inc.	Title Regulator	ory Consultant			Telephone (202) 828-	No. (Include	د در (See Area Code	a)	
	edge tha	tatements I have made o at any knowingly false o able law.		ind all attach					6. Date Ap Receive	ed c Stamped)		
2. Signature Micant Raw				3. Title Regulatory Consultant to Revere Copper Products, Inc.				, ((((((,	(
4. Typed Name Micah T. Reynolds				5. Date August 15. 2012					ι ((,	



Technology Sciences Group Inc.

1150 18th Street, Suite 1000 Washington, DC 20036 Direct: (202) 828-8967 Fax: (202) 872-0745 E-Mail: MReynolds@TSGUSA.com

Micah T. Reynolds Regulatory Consultant

August 15, 2012

Revere Copper Products, Inc. **Label Notification for Revere Antimicrobial** Copper™; EPA Reg. No. 85341-1

Mr. Marshall Swindell, PM-33 Antimicrobials Division (7504P) Office of Pesticide Programs U.S. Environmental Protection Agency **Document Processing Center** Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, Virginia 22202

Dear Mr. Swindell:

Technology Sciences Group, Inc., on behalf of Revere Copper Products, Inc., is submitting the enclosed label notification to add an optional marketing logo for use on the copper alloy product label and/or the fabricated product label. Conventionally, a redline version of the revised label (showing changes made) would be provided; however, since only the logo has been added (creating a ninth page of the label) with no other changes, a redline label was not produced. Please find enclosed the following documents supporting this notification:

- 1) Application for Notification (EPA Form 8570-1);
- 2) Three (3) copies of revised product labeling.

If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8967 or by e-mail at mreynolds@tsgusa.com.

Sincerely,

Regulatory Consultant to Revere Copper Products, Inc.

Enclosures

CC: T. O'Shaughnessy (Revere Copper Products, Inc.)

Washington, D.C.

1150 18th St., NW. Suite 1000 Washington, D.C. 20036

Phone: (202) 223-4392

California

712 Fifth St., Suite A Davis, CA 95616

Phone: (530) 757-1245

Canada

275 Slater St., Suite 900 Ottawa, Ontario K1P 5H9

Phone: (613) 247-6285



Revere Antimicrobial CopperTM 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

96.2%

Other

3.8%

Total

100%

EPA Registration No. 85341-1 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™

NOTIFICATION
Date Reviewed:

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, 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 CopperTM Antimicrobial Copper Alloys and fabricated products made from Revere Antimicrobial CopperTM Antimicrobial Copper Alloys under EPA Registration Number 85341-1.

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
- o Over-bed tables
- o 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,
- o 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)

- o Equipment carts (horizontal surfaces, frames, handles)
- o Door push plates, kick plates, mop plates, stretcher plates
- o Sinks: spigots, drains, sinks themselves
- o Faucet: handles, spigot, drain control lever
- O Water fountains: bubbler head, drain strainer, handle
- o 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
- o Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- o Door handles, doorknobs (outer touch surfaces)
- o Grab bars in bathrooms showers and bathtubs
- o Panic bars on emergency room doors

NOTIFICATION
Date Reviewed: 413/13
Reviewed By:

- 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
- Closures
- Vertical locking arms
- o Vertical cover guards
- o Protection bars
- o Light switches, switch plates
- o Visitor chairs: armrests, metal frames
- o 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
- o Ceiling tiles (non-porous)
- o 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, knurled, push/pull, T-handle, tapered, and ball knobs

- o Intravenous (IV) poles, bases, hangers, clips
- o 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
- o Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- o Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- o Lighting products: X-ray illuminators, operating rooms, patient examination of rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges).
- o 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

NOTIFICATIONS

Date Reviewed:

Reviewed By:

Revere Antimicrobial Copt (EPA Reg. No. 85341-1) Master Label version dated August 13, 2012

- Critical care cart: Table top, drawer, drawer pull, lock, copper wire baskets for storage of equipment and charts.
- o 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
- o Grab handles on privacy curtains
- o Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- o Closet rods and hangers
- o Television controls: knobs, buttons, remote
- o Monitor (television, computer, etc.) housing
- Cup Holder
- o Toothbrush holder
- o Soap holder
- o Magazine rack
- o Signage
- Coat rack and hooks
- Shower curtain rings
- o Radiator cover
- o Bracelets
- o Pens
- o Badge clips
- o Name tags
- o Patient gown snaps
- o Window sills, pulls and locks
- o Electrical wallplates

Community Facilities (including various public and commercial buildings)

- o Shopping cart handles, child seats, handrails
- o Cash registers: housing, keypads
- o ATM machines: keys, housing
- o Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- 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
- o Soap holder
- o Soap dispenser (wall mounted): push bar and dispenser itself
- o Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- o Toilet paper dispenser (housing)
- o Windows (crank), Locking mechanism, pull handles
- o Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- o Casement (cranks, levers, hinges)
- o Single and double-hung windows (locks and pulls)
- o Light switches, switch plates

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- 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)
- Window sills
- o Electrical wallplates
- o Clip boards
- o Office supplies: paper clips, staplers, tape dispensers

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
- Handrails
- Stair rails
- o Door push plates
- o Sinks: spigots, drains, sinks themselves
- o Faucet: handles, spigot, drain control lever
- o Paper towel holders, facial tissue holders, toilet paper holders
- o Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Showerheads
- o Countertops and tabletops
- 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
- Light switches, switch plates
- o Thermostat covers, control knobs and wheels
- o Telephone handsets and surfaces (housings), keypad
- o Floor tiles
- o Ceiling tiles (non-porous)
- o Wall tiles
- o Computer keyboards: keys, housings, computer mouse surfaces
- o Exercise equipment, handles, bars
- o Windows (crank), Locking mechanism, pull handles
- o Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- o Jalousie Windows (crank)



Revere Antimicrobial Copi (EPA Reg. No. 85341-1) Master Label version dated August 13, 2012

- o Casement (cranks, levers, hinges)
- o 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
- o Closet rods and hangers
- o Television remote
- o Cup Holder
- o Toothbrush holder
- o Soap holder
- o Magazine rack
- o Coat rack and hooks
- o Shower curtain rings
- o Radiator cover
- 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
- o Door handles, door knobs (outer touch surfaces)
- o Grab bars and handles
- o 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)

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring
- o Chapel pews
- o Eye glass frames and protective eye wear
- o Pens
- o Combs
- Ashtrays

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

NOTIFICATION

Date Reviewed: 9/3/3

Reviewed By: 9.

Revere Antimicrobial CopperTM – Fabricated Products

The Revere Antimicrobial CopperTM fabricated products listed above may be sold and distributed under EPA Registration Number 85341-1. Products fabricated with Revere Antimicrobial CopperTM Antimicrobial Copper Alloys must bear the EPA approved fabricated product label, below, with one or more of the listed claims.

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

Active Ingredient:

Copper96.2% Other...... 3.8% 100.0%

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

Net Weight: XXX lbs XXX ounces of 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

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 Est. No. . [Product Manufacturer Number]-'35341-NY-001 EPA Reg. No. 85341-1 Manufactured by: [Product Manufacturer Company Name and Address]
Revere Copper Products, Inc. One Revere Park Rome, New York 13440

Date Reviewed: Reviewed By:

Revere Antimicrobial CopperTM (EPA Reg. No. 85341-1) Master Label version dated August 13, 2012

[Optional Logo for Use with Alloy Label or Fabricated Product Label]

Antimicrobial Copper



NOTIFICATION

Date Reviewed: 9/13/