

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 15 2070

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Heather Bjornson Regulatory Consultant for, c/o Revere Copper Products, Inc. TSG, Inc. 1150 15th Street, N.W. Suite 1000 Washington, D.C. 20036

Subject: Revere Antimicrobial Brass EPA Registration Number 85341-2 Your Notification Dated May 19th, 2010 EPA Received Date May 20th, 2010

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add a hang tag and technical bulletin to accompany the product labeling, is acceptable.

Please note that the hang tag and technical bulletin must be submitted with the product labeling when making labeling revisions.

The notification has been made part of the file.

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

Sincerely,

Marshall Swindell Product Manager 33 Regulatory Management Branch I Antimicrobials Division(7510P)

\$EPÁ	United States EPA Environmental Protecti Weshington, DC 20				Registration Amendment Other		O. Approval expires 2-28-9 OPP Identifier Number	
		Applicatio	n for Pesticid	e - Sectior	n I			
1. Company/Product Number			2. EPA P		3. Pro	3. Proposed Classification		
4. Company/Product (Name)			Marshall Swindell [√] None [] Re					Restricted
Revere Antimicrobial			33					
5. Name and Address of Applicant <i>(Include ZIP Code)</i> Revere Copper Products, Inc. One Revere Park Rome, NY 13440			6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No					
Check if th	his is a new address		Produc	t Name				
			Section - II					
Notification - Expla Explanation: Use additi This notification is add sub This notification is consiste labeling of the Confidential EPA. I further understand FIFRA and I may be subje	ional page(s) if necessar blabels with already appro ent with the provisions of f I statement of formula of t that if this notification is r	oved text, to clari PR Notice 98-10 this product. 1 ur not consistent wil	a I and Section II.) fy a claim for the state and EPA regulations inderstand that it is a v th the terms of PR No	at 40 CFR 152. violation of 18 U. viice 98-10 and 4	other minor text re 46, and no other S.C. Sec. 1001 to	changes h willfully π	ave been ma take any false	de to the statement t
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EPA I	Form	8570-1	(Rev.	3-94)	Previous	editions	are	obsolete.
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WASHINGTON

1150 18th Street, N.W. Suite 1000 Washington, D.C. 20036 Telephone 202 223-4392 Fax 202 872-0745

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Marshall Swindell Karen Leavy Office of Pesticide Programs US Environmental Protection Agency One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202

RE: Revere Copper Products, Inc. Revere Antimicrobial Brass (EPA Reg. No. 85341-2)

SACRAMENTO

712 Fifth Street Suite A Davis, CA 95616 Telephone 530 757-1298 Fax 530 757-1299

CANADA 275 Slater Street Suite 900 Ottawa, Ontario K1P 5H9 Telephone 613 247-6285 Fax 613 236-3754 Notification to add sublabels, a technical bulletin, and other minor text Revisions per PR-Notice 98-10.

May 19, 2010

Dear Mr.Swindell:

Technology Sciences Group, Inc., on behalf of Revere Copper Products, Inc., is submitting the enclosed notification to add sublabels, a technical bulletin, both based on EPA approved language, and consistent with the Copper Development Association labels. Enclosed you will find the notification application form and one copy of the redline label.

Please do not hesitate to contact me with any questions at(202) 828-8945 or via email: <u>hbjornson@tsgusa.com</u>.

Sincerely,

Aleather R Bron

Heather R. Bjornson Regulatory Consultant to Revere Copper Products, Inc.

Revere Antimicrobial Brass

Active Ingredient: Copper 73.1%[#] Other 26.9%[#] [#] Nominal percentages for purpose of review and approval. Actual percentage of copper and other ingredients will be indicated on labels distributed with the product.

Sublabel II. -- Component Label and Accompanying Technical Bulletin

Total

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Master Label containing:

Sublabel I. - Complete Label

100%

EPA Registration No. ***** 8534/-2 EPA Establishment No. *****

Manufactured by: Revere Copper Products, Inc. One Revere Park Rome, NY 13440

Net ContentsWeight: XXX lbs XXX ounces of [brand name]******

Revere Antimicrobial Brass (EPA Reg. No. 85341-2) Label version (5) dated May 14, 2010

Revere Antimicrobial Brass

Laboratory testing has shown that when cleaned regularly:

[Antimicrobial Copper Alloys continuously reduce bacterial* contamination, achieving 99.9% reduction within two hours of exposure.]

[Antimicrobial Copper Alloys surfaces kill greater than 99.9% of Gram-negative and Gram-positive bacteria* within two hours of exposure.]

[Antimicrobial Copper Alloys surfaces deliver continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within two hours, even after repeated wet and dry abrasion and re-contamination.]

[When cleaned regularly, Antimicrobial Copper Alloys surfaces kill greater than 99.9% of bacteria* within two hours, and continue to kill more than 99.9% of bacteria* even after repeated contamination.]

[Antimicrobial Copper Alloys surfaces help inhibit the buildup and growth of bacteria* within two hours of exposure between routine cleaning and sanitizing steps.]

[This product 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.]

* Testing demonstrates effective antibacterial activity against *Staphylococcus aureus*, *Enterobacter aerogenes*, Methicillin-Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* O157:H7, and *Pseudomonas aeruginosa*.

The use of Copper Alloy Surfaces 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 relating to cleaning and disinfection of environmental surfaces. The Copper Alloy surface material has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.

Active Ingredient: Copper 73.1%# 26.9% Other [#] Nominal percentages for purpose of review and approval. Actual percentage of copper and other ingredients will be indicated on labels distributed with the product. Total 100% ້ເເວຍ Manufactured by: $b_{b_0}^{c_0} = b_{b_0}^{c_0} = b_{c_0}^{c_0}$ EPA Registration No. **** 8534/-2 EPA Establishment No. ***** Revere Copper Froducts, Ing. One Revere Park Net ContentsWeight: XXX lbs XXX ounces of [brand name]****** Rome NY 13440 G erce ددرد د

> Revere Antimicrobial Brass (EPA Reg. No. 85341-2) Label version (5) dated May 14, 2010

DIRECTIONS FOR USE

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

[The directions in bracketed text below may be included in an insert. If so, there will be a statement to see the insert for additional directions for uses of the product.]

[Directions for Use in the insert also may include installation and operation instructions, user manuals, and similar instructional materials appropriate for the end use product. No additional pesticide claims will be made as part of these materials.]

Proper Care and Use of Antimicrobial Copper Alloys: The use of Antimicrobial Copper Alloys does not replace standard infection control procedures and good hygienic practices. Antimicrobial Copper Alloys surfaces must be cleaned and sanitized according to standard practice. Health care facilities must maintain the product in accordance with infection control guidelines; users must continue to follow all current infection control practices, including those practices related to disinfection of environmental surfaces.

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

This product must not be waxed, painted, lacquered, varnished, or otherwise coated.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of the Antimicrobial Copper Alloy surface. Cleaning agents typically used for traditional touching surfaces are permissible; the appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. [Normal tarnishing or wear of Antimicrobial Copper Alloy surfaces will not impair the antibacterial effectiveness of the product.]

This product can not be used for any direct food contact or food packaging uses.

[Antimicrobial Copper Alloys may be used in hospitals, other healthcare facilities, and various public, commercial, and residential buildings for the non-food contact surfaces listed below.] [The following statement will appear on the label if the use involves potential exposure to outdoor conditions: Surfaces that may be exposed to outdoor environmental conditions (*e.g.*, handrails, shopping carts, child seats and ATM machines) are not representative of indoor laboratory test conditions, and therefore, may impart reduced efficacy if not cleaned when visibly soiled.]

Healthcare Facilities

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- Bedrails, footboards
- o 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 pusk plates
- o 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 cal

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

- Equipment carts (horizontal surfaces, frames, handles) 0
- Door push plates, kick plates, mop plates, stretcher plates 0
- Sinks: spigots, drains, sinks themselves 0
- Faucet: handles, spigot, drain control lever 0
- Water fountains: bubbler head, drain strainer, handle 0
- Alcohol sanitizer dispenser, handle 0
- Paper towel holders, facial tissue holders, toilet paper holders 0
- 0 Air hand dryer, controls and push buttons on air hand dryers
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces 0 without water contact)
- Door handles, doorknobs (outer touch surfaces) 0
- Grab bars in bathrooms showers and bathtubs 0
- Panic bars on emergency room doors 0
- Towel bars 0

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- Showerheads 0
- Countertops and tabletops (non-food use only) 0
- Hinges, locks, latches, and trim 0
- Door stops, door pulls, and protector guards 0
- Toilet and urinal hardware, levers, push buttons 0
- Toilet seat inlay for lifting of seat 0
- 0 Closures
- Vertical locking arms 0
- Vertical cover guards 0
- Protection bars 0
- Light switches, switch plates 0
- Visitor chairs: armrests, metal frames 0
- Thermostat covers, control knobs and wheels 0
- Telephone handsets and surfaces (housings), keypad 0
- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, 0 refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles 0
- Ceiling tiles 0
- Wall decorative tiles 0
- Instrument handles 0

Medical equipment knobs, pulls and handles for:

- Drug delivery systems ٠
- 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 666666

- Intravenous (IV) poles, bases, hangers, clips 0
- Trays (instruments, non-food contact) 0
- Pans (bed) 0
- Walkers, wheelchair handles, and tubular components 0
- Computer keyboards: keys, housings, computer mouse surfaces 0
- Exercise and rehabilitation equipment, handles, bars 0

Revere Antimicrobial Brass (EPA Reg. No. 85341-2) Label version (5) dated May 14, 2010

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- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables $\mathscr{C}//\mathcal{A}$
- Chairs (shower chairs, Lient chairs, visitor chairs): rails, backs gs, 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
- Storage Shelving: wire shelving etc. for medical supplies
- o Grab handles on privacy curtains
- o Lids of laundry hampers, trash canisters, and other containers

Community Facilities (including various public and commercial buildings)

- o Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- ATM machines: keys, housing
- o Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Ice and water dispensers (outer surfaces without water contact)
- o Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- o Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- $\circ \quad \text{Soap holder} \quad$
- Soap dispenser (wall mounted): push bar and dispenser itself
- Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- o Jalousie Windows (crank)
- o Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- o Light switches, switch plates
- o Lids of laundry hampers, trash canisters, and other containers

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)

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o Towel bars

- o Showerheads
- Countertops and tablet
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- o Light switches, switch plates
- Thermostat covers, control knobs and wheels
- o Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Ceiling tiles
- o Wall decorative tiles
- 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)
- Jalousie Windows (crank)
- o 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

Other

• Playground equipment (outdoor): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring

Outdoor uses are limited to those specified in the above list.

STORAGE AND DISPOSAL

ANTIMICROBIAL COPPER ALLOYS should be disposed in a responsible manner, including recycling.

WARRANTY STATEMENT

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

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Sublabel II - Component Label and Accompanying Technical Bulletin

reduction within 2 hours of exposure. - This surface kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within 2 hours of exposure. - This surface delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours. - This surface delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours. - This surface delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours. - This surface hills greater than 99.9% of bacteria* within 2 hours. - This surface helps inhibit the buildup and growth of bacteria* within 2 hours of exposure between routine cleaning and sanitizing steps. - This product is made (out of)(from) a (copper)(touch) surface that continuously kills bacteria for Directions for Use let Weight: XXX lbs XXX ounces of	<u>FRONT</u>	BACK /o
 Head minimission of encounter o		
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<section-header></section-header>	Rovere	
<pre>deture ingredion:</pre>		bacteria* within 2 hours of exposure.
<section-header></section-header>	Antimicrobial	
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The use of this product is a supplement to and not a substitute for standard infection control practices, inducing influes practices related to cleaning and disinfection of any information built does not necessarily prevent cross containingation. DIRECTON FOR USE The surfaces. This surface is an above the information of the end of the		
Infection control nearcies: users must continue to follow all current infection control nearcies. This surfaces have been shown to reduce mitorobia contamination. but it does not necessarily prevent cross contamination. It is a violation of Federal law to use this consistent with its labeling. Fractices, This surfaces, This surface, Sur		(MICSA), Escherichia con OTST.HT, Escudomonas aeruginosa.
<pre>control practices. Induding those procession prevent cross contamination, built does not necessarily prevent cross contamination.</pre>		
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Revere Antimicrobial Brass (EPA Reg. No. 85341-2) Label version (5) dated May 14, 2010 7

TECHNICAL BULLETIN

REVERE ANTIMICROBIAL COPPER EPA Reg. No. 85341-2

This product may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the non-food contact surfaces listed below.

Healthcare Facilities

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- o Bedrails, footboards
- Over-bed tables
- <u>Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)</u>
- o Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- o Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- o Bedrails, assistance rails,
- o Toilet safety rails
- <u>o</u> 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
- <u>Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces</u> 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
- o 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
- Vertical cover guards
- o Protection bars
- o Light switches, switch plates
- o Visitor chairs: armrests, metal frames

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- o Thermostat covers, con I knobs and wheels
- o _____Telephone handsets and surfaces (housings), keypad
- <u>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)</u>
- o Floor tiles
- Ceiling tiles
- o Wall decorative tiles
- 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
- 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
- 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)
- <u>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.</u> Baskets, monitor housings, knobs, baskets, tables, IV poles
- o 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

Community Facilities (including various public and commercial buildings)

- 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, c f
- o Ice and water dispensers (outer surfaces without water contact)
- o Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- o Soap holder

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- o Soap dispenser (wall mounted): push bar and dispenser itself
- o Soap dispenser (sitting counter): dispenser housing itself, pul nechanism
- o Toilet paper dispenser (housing)
- o Windows (crank), Locking mechanism, pull handles
- o Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- o Jalousie Windows (crank)
- o Casement (cranks, levers, hinges)
- o Single and double-hung windows (locks and pulls)
- o Light switches, switch plates
- o Lids of laundry hampers, trash canisters, and other containers

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

- <u>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)</u>
- o Bedrails, footboards
- <u>o Handrails</u>

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- o 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)
- o Grab bars in bathrooms showers and bathtubs
- o Towel bars
- o 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
- o Light switches, switch plates
- o Thermostat covers, control knobs and wheels
- o Telephone handsets and surfaces (housings), keypad
- o Floor tiles
- o Ceiling tiles
- o Wall decorative tiles
- o Computer keyboards: keys, housings, computer mouse surfaces
- o Exercise equipment, handles, bars

<u>0</u>	Windows (crank), Locking mechanism, pull handles		6655 6 8		
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Other

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 <u>Playground equipment (outdoor)</u>: bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring

Surfaces that may be exposed to outdoor environmental conditions (*e.g.*, handrails, shopping carts, child seats and ATM machines) are not representative of indoor laboratory test conditions, and therefore, may impart reduced efficacy if not cleaned when visibly soiled.]

Revere Copper Products, Inc. One Revere Park Rome, NY 13440

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