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EPA United States Environmental Protection Office of Pesticide Programs

Globe Brass and Copper Inc. 427 North Shamrock Street East Alton, IL 62024

85353-1

Attention: Micah T. Reynolds

Subject: CuVerro® I EPA Registration No. 85353-1 Notification Dated December 3, 2012

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9).

Proposed Notification

Additional Brand Name: CuVerro® I Bactericidal Copper Surfaces"

General Comments

Based on a review of the submitted material, the following comments apply.

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely. Jerry / Jon

Marshall Swindell Product Manager (33) Regulatory Management Branch 1 Antimicrobials Division (7510P)

Pager glued Stenciled Other Correct Correct I. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this afiplicition.) Telephone No. Image: Code) Name Title Telephone No. (Include Area Code) Micah T. Reynolds, Technology Sciences Group, Inc. Title Telephone No. S. Date Application I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. S. Title S. Title Regulatory Consultant Correct Code Correct Code Code Code 3. Title Regulatory Consultant to Global Brass and Copper, Inc. Copper, Inc. Code Code	United States Environmental Protection A Washington, DC 20460 Application for Company/Product Number 85353-1 Company/Product (Name) CuVerro® I Name And Address Of Applicant (Include ZIP Code) Global Brass and Copper, Inc. 27 North Shamrock Street East Alton, Illinois 62024 Check if this is a new address	Agency r Pesticide – Sec 2. EPA Product Ma Marsh PM# 33 6. Expedited Re (b)(i), my product to: EPA Reg. No Product Name _	Registration Amendment Amendment Other Other other nager nall Swindell eview. In accordance t is similar or identica	OPP Identifier Number 3. Proposed Classification X None Restricted xe with FIFRA Section 3(c)(3)
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Section II Amendment - Explain below. Final Printed labels in response to Agency letter dated	S			
Amendment – Explain below. Agency letter dated				
Submission of Label Notification to add additional alternate brand name. his notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the abeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement of provisions of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of 18 U.S.C. Sec. 1001 to willfully make any false statement of provisions of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of 18 U.S.C. Sec. 1001 to willfully make any false statement of provisions of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of 18 U.S.C. Sec. 1001 to willfully make any false statement of provide actions 12 and 14 of FIFRA. Please confirm receipt with Micah Reynolds: merynolds@tsgusa.com, phone (202) 828-8967, or fax (202) 872-0745. Section III Material This Product Will Be Packaging 2. Type of Container Water Soluble Packaging 2. Type of Container Plastic Certification must If Yes" No. per Water Soluble Packaging wgt. Container Plastic I Location of Net Contents Information 4. Size(S) Retail Container 5. Lacation of Label Directions on Labeling accomparity profest duct Paper Other Specify (Profest duct I Label Container 111 Telephone/No. (Include Ares: Code) (202) R38.3967 Cercic Code Code (202) C		Final Printec Agency lette	er dated oplication.	
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1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Title Micah T. Reynolds, Technology Sciences Group, Inc. Title Certification (202),938-9967 I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. S. Title 2. Signature 3. Title Regulatory Consultant to Global Brass and Copper, Inc. 4. Typed Name 5. Date 5. Date		ection IV		
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	Regul	latory Consultant	to Global Brass a	
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P/	Form	8570-1	(Rev. 8-94)	Previous editions	are obsolete



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

December 3, 2012

Global Brass and Copper, Inc. Label Notification for CuVerro® I; EPA Reg. No. 85353-1

Mr. Marshall Swindell, PM-33 Antimicrobials Division (**7510P**) Office of Pesticide Programs (**NOTIF**) 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 Global Brass and Copper, Inc., is submitting the enclosed label notification to add an alternate brand name to the master label of the above referenced product. Global Brass and Copper, Inc. seeks to add "CuVerro Bactericidal Copper Surfaces" as an alternate brand name to the product label. Please find enclosed the following documents supporting this notification:

- 1) Application for Notification (EPA Form 8570-1);
- 2) One (1) copy of the label with changes highlighted;
- 3) 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 Global Brass and Copper, Inc.

Enclosures

CC: M. Visnack (Global Brass and Copper, 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 SH9 Phone: (613) 247-6285

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CuVerro[&] 1 (EPA Reg. No. 85353-1) Master Label version dated December 3, 2012

[Alternate Brand Names:

CuVerro® I Antimicrobial Copper Alloy] CuVerro® I Bactericidal Copper Surfaces]

CuVerro[®] I AND ASSOCIATED FABRICATED PRODUCTS MASTER LABEL

The Master Label consists of the label that will accompany the CuVerro[®] I Antimicrobial Alloys and a label that will accompany each product fabricated using a registered CuVerro[®] I alloy.

[Alloy Label – Front Panel]

CuVerro[®] I AND ASSOCIATED FABRICATED PRODUCTS

Active Ingredient: Copper Other

66.5% 33.5%

Total

100%

EPA Registration No. 85353-1 EPA Establishment No. 85353-XX Made in the United States by: Global Brass and Coppers Inc. 427 N. Shamfock Street East Alton, JL 62024

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Net Weight: XXX lbs XXX ounces of CuVerro[®] I

[See insert (side panel) (back panel) for Directions for Use]

DIRECTIONS FOR USE

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

CuVerro[®] I Antimicrobial Copper Alloys

This alloy is 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 CuVerro[®] I Antimicrobial Copper Alloys and fabricated products made from CuVerro[®] I Antimicrobial Copper Alloys under EPA Registration Number 85353-1.]

A list of components that may be fabricated out of CuVerro[®] I Antimicrobial Copper Alloys is specified below. CuVerro[®] I 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,
- 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)

• Equipment carts (horizontal surfaces, frames, handles)

- Door push plates, kick plates, mop plates, stretcher plates
- Sinks: spigots, drains, sinks themselves
- o Faucet: handles, spigot, drain control lever
- Water fountains: bubbler head, drain strainer, handle
- Alcohol sanitizer dispenser, handle
- 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)
- Grab bars in bathrooms showers and bathtubs
- Panic bars on emergency room doors
- Towel bars

CuVerro[®] I⁻(EPA Reg. No. 85353-1) Master Label version dated December 3, 2012

o Showerheads

• Countertops and tabletops (non-food use only)

- o 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 Closures
- o Vertical locking arms
- Vertical cover guards
- o Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames
- Thermostat covers, control knobs and wheels
- 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)
- o Floor tiles
- Ceiling tiles (non-porous)
- o Wall 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

- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- Pans (bed)
- Walkers, wheelchair handles, and tubular components
- 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 color units (lamp housings and adjustable arms), CRT monitors with rotating knobs, and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV

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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, 0 toilet handle, door and cabinet facings, counter tops

Medical records: Chart holders, clipboards, filing systems 0

Storage Shelving: wire shelving etc. for medical supplies ò

Grab handles on privacy curtains 0

• Lids of laundry hampers, trash canisters, and other containers

Bedside pitchers 0

Closet rods and hangers 0

Television controls: knobs, buttons, remote 0

Monitor (television, computer, etc.) housing 0

Cup Holder 0

Toothbrush holder 0

Soap holder 0

Magazine rack 0

Signage 0

Coat rack and hooks 0

Shower curtain rings 0

Radiator cover 0

Bracelets 0

Pens 0

Badge clips 0

0 Name tags

Patient gown snaps 0

Window sills, pulls and locks 0

Electrical wallplates 0

Community Facilities (including various public and commercial buildings)

Shopping cart handles, child seats, handrails 0

Cash registers: housing, keypads 0

ATM machines: keys, housing 0

o Gym/Health club lockers, locker handles, locker shelving, trainers' tables,

Ice and water dispensers (outer surfaces without water contact) 0

Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior catico co 0 button plate

Paper towel dispensers. Housing itself, (turn) handle, (push) handle 0

Soap holder 0

Soap dispenser (wall mounted): push bar and dispenser itself 0

Soap dispenser (sitting on counter): dispenser housing itself, push mechanism 0

Toilet paper dispenser (housing) 0

Windows (crank), Locking mechanism, pull handles 0

Window treatments (cord pulls), Venetian blinds (wands, cord pulls) 0

Jalousie Windows (crank) 0

Casement (cranks, levers, hinges) 0

Single and double-hung windows (locks and pulls) 0

o Light switches, switch plates

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CuVerro® I (EPA Reg. No. 85353-1) Master Label version dated December 3, 2012

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- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- o Signage
- Coat rack and hooks
- Shower curtain rings
- o Radiator cover
- o Bracelets
- o Badge clips
- Name tags
- Vending machines (non-food contact only)
- o Window sills
- o Electrical wallplates
- Clip boards
- 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
- o Handrails
- o Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- 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
- Showerheads
- Countertops and tabletops
- 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
- Light switches, switch plates
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- o Floor tiles
- Ceiling tiles (non-porous)
- o Wall tiles
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)

T (EPA Reg. No. 85353-1) CuVerro Master Label version dated December 3, 2012

o Casement (cranks, levers, hinges)

- Single and double-hung windows (locks and pulls)
- o Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- o Television remote
- Cup Holder 0
- o Toothbrush holder
- Soap holder 0
- Magazine rack 0
- Coat rack and hooks 0
- Shower curtain rings
- o Radiator cover
- Window sills
- o Electrical wallplates
- o Baby cribs: rails, fittings, brackets, supports
- o Bowl stands
- Office supplies: paper clips, staplers, tape dispensers
- Monitor (television, computer, etc.) housing 0

Mass Transit Facilities

- o Handrails
- o Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- o Grab bars and handles
- Tiles: wall, floor, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- o Signage
- Vending machines (non-food contact only) 0

Other

- o Play area equipment (indoor only): bars, handles, chains, push plates, handrails, oolo stair rails and risers, wheels, knobs, flooring с
- Chapel pews
- Eye glass frames and protective eye wear
- o Pens
- o Combs
- Ashtrays 0

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

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CuVerro®`1 (EPA Reg. No. 85353-1) Master Label version dated December 3, 2012

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<u>CuVerro[®] I – Fabricated Products</u>

The CuVerro[®] I fabricated products listed above may be sold and distributed under EPA Registration Number 85353-1. Products fabricated with CuVerro[®] I 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.

CuVerro T (EPA Reg. No. 85353-1) Master Label version dated December 3, 2012

CuVerro[®] I **Fabricated Product Label**

BACK

FRONT

[This (touch surface) (product)] made from
CuVerro [®] I
Active Ingredient:
Copper
Other
[Total 100.0%]
See [Back/Side Panel][Insert] for Directions for
Use
Net Weight: XXX lbs XXX ounces of CuVerro®
I

CuVerro[®] I

- 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 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 quidelines. 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. CCCCCO

Not approved for direct food contact or food packaging uses. ge

c 000000 [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.]

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STORAGE AND DISPOSAL

Dispose of by recycling or put in trash. LEEEE

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]- 05353-XX EPA Reg. No. 85353-1 Manufactured by: [Product Manufacturer Company Name and Address] Global Brass and Copper, Inc. 427 North Shamrock Street East Alton, IL 62024

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CuVerro[®] I (EPA Reg. No. 85353-1) Master Label version dated December 3, 2012 12/12

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

Antimicrobial Copper



CuVerro® CuVerro®

Antimicrobial Copper Surfaces

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