

85353-4

(7/29/2013

1/12



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

JUL 29 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Micah T. Reynolds, Regulatory Consultant to Global Brass and Copper Inc.
Global Brass and Copper, Inc.
427 North Shamrock Street
East Alton, IL 62024

Subject: Notification; Per PR-Notice 98-10
Product Name: CuVerro IV
EPA Registration Number: 85353-4
Application Date: May 14, 2013

Dear Mr. Reynolds:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated May 14, 2013 for the product referenced above. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10. The label with the updated non-food use sites, alternate verbiage, and logo submitted with the application is acceptable and will be placed in our records.

If you have any questions regarding this letter, please contact Amaris Johnson at (703) 305-9542 or johnson.amaris@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "M Swindell".

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

2/12

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide – Section I

1. Company/Product Number 85353-4	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CuVerro® IV	PM# 33	
5. Name And Address Of Applicant (Include ZIP Code) Global Brass and Copper, Inc. 427 North Shamrock Street East Alton, Illinois 62024 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain Below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of Label Notification to update non-food use sites (consistent with parent product), add descriptive text consistent with antimicrobial claims, and add logo consistent with alternate brand name.

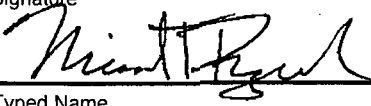
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please confirm receipt with Micah Reynolds: mreynolds@tsgusa.com, phone (202) 828-8967, or fax (202) 872-0745.

Section III

1. Material This Product Will Be Packaged In:					
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container		
* Certification must be submitted			If "Yes" Unit Packaging wgt.	No. per Container	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
			If "Yes" Unit Packaging wgt.	No. per Container	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithographed <input type="checkbox"/> Pager glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____		

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Micah T. Reynolds, Technology Sciences Group, Inc.	Title Senior Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8967
Certification 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.		6. Date Application Received (Stamped)
2. Signature 		
3. Title Regulatory Consultant to Global Brass and Copper, Inc.		
4. Typed Name Micah T. Reynolds		5. Date May 14, 2013

3/12



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
Senior Regulatory Consultant

May 14, 2013

Global Brass and Copper, Inc.
Label Notification for CuVerro® IV;
EPA Reg. No. 85353-4

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: 1) update the non-food use sites (products from which the product may be fabricated) consistent with the same recent updates made by the Copper Development Association's parent product (82012-1); 2) add alternate verbiage (i.e. "bactericidal") to select antimicrobial claims that are consistent with the original claim; and 3) add a logo consistent with a previously approved alternate brand name. 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@tsqusa.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 5H9
Phone: (613) 247-6285

4/12

[Alternate Brand Names: CuVerro® IV Antimicrobial Copper Alloy]
CuVerro® IV Bactericidal Copper Surfaces]

CuVerro® IV
AND ASSOCIATED FABRICATED PRODUCTS
MASTER LABEL

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

[Alloy Label – Front Panel]

CuVerro® IV
AND ASSOCIATED FABRICATED PRODUCTS

Active Ingredient:

Copper	96.2%
Other	3.8%
Total	100%

EPA Registration No. 85353-4
EPA Establishment No. 85353-XX

Made in the United States by:
Global Brass and Copper, Inc.
427 N. Shamrock Street
East Alton, IL 62024

Net Weight: XXX lbs XXX ounces of CuVerro® IV

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

NOTIFICATION
Date Reviewed: 7/29/13
Reviewed By:

DIRECTIONS FOR USE

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

CuVerro® IV Antimicrobial Copper Alloys

This alloy is 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 CuVerro® IV Antimicrobial Copper Alloys and fabricated products made from CuVerro® IV Antimicrobial Copper Alloys under EPA Registration Number 85353-4.]

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

Touch Surface Components

Healthcare Facilities

- Bedrails, footboards
- Over-bed tables
- Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)
- 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)
- 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
- 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

6/12

- Towel bars
- Showerheads
- Countertops and tabletops (non-food use only)
- 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
- Closures
- Vertical locking arms
- Vertical cover guards
- 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)
- Floor tiles
- Ceiling tiles (non-porous)
- 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
- 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
- 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

7/12

- 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
- Medical records: Chart holders, clipboards, filing systems
- Storage Shelving: wire shelving etc. for medical supplies
- Grab handles on privacy curtains
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television controls: knobs, buttons, remote
- Monitor (television, computer, etc.) housing
- Cup Holder
- Toothbrush holder
- Soap holder, dispenser
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Pens
- Badge clips
- Name tags
- Patient gown snaps
- Window sills, pulls and locks
- Electrical wallplates

Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- ATM machines: keys, housing
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Exercise equipment, handles, bars
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- 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)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)

8/12

- Light switches, switch plates
- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Badge clips
- Name tags
- Vending machines (non-food contact only)
- Window sills
- 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)
- Bedrails, footboards
- Handrails
- 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
- Floor tiles
- Ceiling tiles (non-porous)
- 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)

9/12

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

Mass Transit Facilities

- Handrails
- 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, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- Signage
- Vending machines (non-food contact only)

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
- Door handles, knobs, latches and locks
- 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

10/12

- Eye glass frames and protective eye wear
- Pens
- Combs
- Ashtrays

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

CuVerro® IV – Fabricated Products

The CuVerro® IV fabricated products listed above may be sold and distributed under EPA Registration Number 85353-4. Products fabricated with CuVerro® IV 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 (bactericidal) properties will remain effective for as long as the product remains in place and is used as directed.

11/12

CuVerro® IV

Fabricated Product Label

FRONT

[This (touch surface) (product)] made from
CuVerro® IV
 Active Ingredient:
 Copper 96.2%
 Other..... 3.8%
 [Total 100.0%]
 See [Back/Side Panel][Insert] for Directions for Use
 Net Weight: XXX lbs XXX ounces of CuVerro® IV

BACK

CuVerro® IV

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* (bactericidal*) 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 (bactericidal) 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 (bactericidal) 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 (bactericidal) properties will remain effective for as long as the product remains in place and is used as directed.

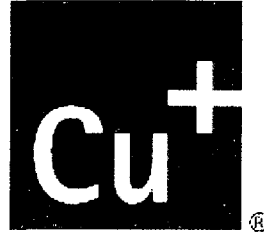
EPA Reg. No. 85353-4 EPA Est. No. [Product Manufacturer Number]- 85353-xx
 Manufactured by: [Product Manufacturer Company Name and Address]
 Global Brass and Copper, Inc. 427 North Shamrock Street East Alton, IL 62024

12/12

CuVerro® IV (EPA Reg. No. 85353-4)
Master Label version dated May 13, 2013

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

Antimicrobial
Copper



CuVerro®

CuVerro®

Bactericidal Copper Surfaces

CuVerro®

Antimicrobial Copper Surfaces