

85353-3

9/20/2012

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

SEP 20 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. M. Visnack
President for,
Global Brass and Copper, Inc.
One Revere Park
Rome, NY 13440

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

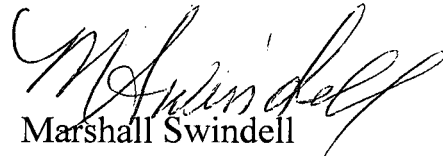
Subject: CuVerro III
EPA Registration Number 85353-3
Your Notification Dated August 20, 2012
EPA Received Date August 21, 2012

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

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	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 85353-3	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CuVerro® III	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.)

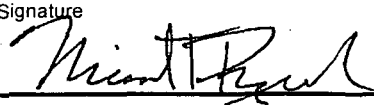
Submission of Label Notification to add marketing logos.
 This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is 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@tsqusa.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 <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	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 checked="" type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

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 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 August 20, 2012	

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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 20, 2012

Global Brass and Copper, Inc.
Label Notification for CuVerro® III;
EPA Reg. No. 85353-3

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 Global Brass and Copper, Inc., is submitting the enclosed label notification to add several optional marketing logos 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.

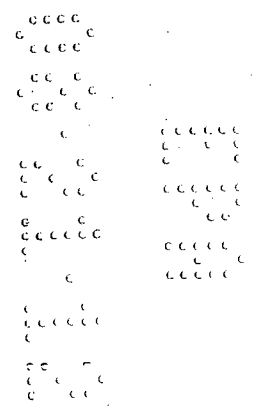
If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8967 or by e-mail at mreynolds@tsgusa.com.

Sincerely,

Regulatory Consultant to
Global Brass and Copper, Inc.

Enclosures

CC: M. Visnack (Global Brass and Copper, Inc.)



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Alternate Brand Name: CuVerro® III Antimicrobial Copper Alloy

**CuVerro® III
AND ASSOCIATED FABRICATED PRODUCTS
MASTER LABEL**

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

[Alloy Label – Front Panel]

**CuVerro® III
AND ASSOCIATED FABRICATED PRODUCTS**

Active Ingredient:

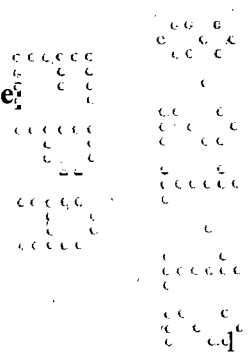
Copper	82.6%
Other	17.4%
Total	100%

EPA Registration No. 85353-3
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® III

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



NOTIFICATION
 Date Reviewed: 7/20/13
 Reviewed By: [Signature]

DIRECTIONS FOR USE

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

CuVerro® III 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® III Antimicrobial Copper Alloys and fabricated products made from CuVerro® III Antimicrobial Copper Alloys under EPA Registration Number 85353-3.]

A list of components that may be fabricated out of CuVerro® III Antimicrobial Copper Alloys is specified below. CuVerro® III 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
- Towel bars

NOTIFICATION
Date Reviewed: 9/20/13
Reviewed By: K. LEAH

- 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

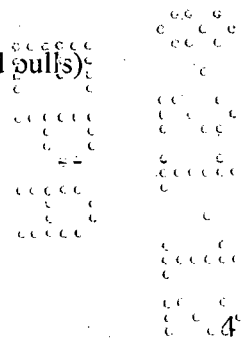
NOTIFICATION
 Date Reviewed: 7/20/12
 Reviewed By: K. Leary

- 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
- 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,
- 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)
- Light switches, switch plates

NOTIFICATION
Date Reviewed: 8/20/12
Reviewed By: L. O'Neil



12/13

CuVerro® III

Fabricated Product Label

FRONT

[This (touch surface) (product)] made from
CuVerro® III
 Active Ingredient:
 Copper 82.6%
 Other.....17.4%
 [Total 100.0%]
 See [Back/Side Panel][Insert] for Directions for Use
 Net Weight: XXX lbs XXX ounces of CuVerro® III

BACK

CuVerro® III

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 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

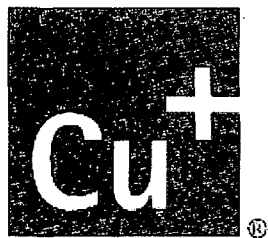
If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

EPA Reg. No. 85353-3 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

NOTIFICATION
 Date Reviewed: 12/30/12
 Reviewed By: H.C. Terry

Optional Logos for Use with Alloy Label or Fabricated Product Label

Antimicrobial
Copper



CuVerro®

CuVerro®

Antimicrobial Copper Surfaces

NOTIFICATION
Date Reviewed: 9/30/12
Reviewed By: K. Lenny