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

NOV 6 6 2009



# United States Environmental Protection Office of Pesticide Programs Agency

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

Attention: Amy Plato Roberts

Subject: Copper Shield 66

EPA Registration No. 85353-1 Notification Dated October 8, 2009

This will acknowledge receipt of your notification to add the following additional brand name, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

### **ADDITIONAL BRAND NAME**

"CuVerro™**™**"

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your product file.

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

Sincerely

Marshall Swindell

Product Manager (33)

Regulatory Management Branch 1 Antimicrobials Division (7510P)

Plassa read instructions on reverse before completing form.	Form Ap	proved. OMB No.	2070-0060	Approval expires 2-28-95	
United State Environmental Protec Weshington, DC 2	tion Agency	Registra Amendr  ✓ Other		OPP Identifier Number	
Application for Pesticide - Section I					
1. Company/Product Number 85353-1	· · · · · · · · · · · · · · · · · · ·	2. EPA Product Manager  Marshall Swindell  3. Proposed Classification  Restricted			
4. Company/Product (Name) Copper Shield 66	PM# 33	PM#		لــــا	
5. Name and Address of Applicant <i>lincjude ZIP Code!</i> Global Brass and Copper Inc. 427 North Shamrock Street East Alton, IL 62024	(b)(i), my product to:	6. Expedited Reveiw. In accordance with FIFRA (b)(i), my product is similar or identical in composit to:  EPA Reg. No.		nposition and labeling	
Check if this is a new address	Product Name				
Section - II					
Amendment - Explain below.    Final printed labels in repsonse to Agency letter dated *Me Too" Application.    Value					
Explanation: Use additional page(s) if necessary. (For section I and Section II.)  Label notification to add an Alternate Brand Name. See attached cover letter dated October 8, 2009 for details.  This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.48, and no other changes have been made to the labeling or the confidential statement of formula for this product. I understand that it is a violation of t8 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.					
Section - III					
1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging  Yes No  * Cartification must be submitted  Unit Packaging  Yes No  If "Yes" Unit Packaging wgt.  No per Contained	Water Soluble Packaging Yes No If "Yes" No. per Package wgt containe	Metal Plastic Glass No. per Paper			
	- On Lohal				
6. Manner in Which Label is Affixed to Product Uthograph Other Stenciled					
Section - IV					
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Amy Plato Roberts / aroberts@tsgusa.com	l l			elephone Nouthmiliée Area Code) 202) 828-8964	
I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.				Received control	
2. Signature	3. Title Regulatory Consultant				
4. Typed Name  Amy Plato Roberts	October 8, 200	9		( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( (	



WASHINGTON

1150 18th Street, N.W.

17

**Suite 1000** 

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Marshell Swindell, PM 33

Regulatory Management Branch I Antimicrobials Division (7510P)

Office of Pesticide Programs, EPA

One Potomac Yard

2777 South Crystal Drive

Arlington, VA 22202

October 8, 2009

RE:

Copper Shield 66; EPA Reg. No. 85353-1

Label NOTIFICATION to add an alternate brand name

Enclosed with this letter you will find the following in support of a label NOTIFICATION, per PR Notice 98-10, to add an alternate brand name to the

No other changes are made to the product label at this time. If you have any questions or comments please contact Heather Bjornson [(202) 828-8945;

**SACRAMENTO** 

712 Fifth Street

Dear Mr. Swindell:

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

1) Notification form:

above referenced product:

hbjornson@tsgusa.com] directly.

2) One (1) copy of the label with all changes highlighted in red.

This label notification is to add the following alternate brand name:

"CuVerro<sub>m</sub>"

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

Sincerely,

**Amy Plato Roberts** 

Regulatory Consultant

Direct dial: (202) 828-8964; E-mail: aroberts@tsgusa.com

E-mail tsg@tsgusa.com

http://www.tsgusa.com

[Front panel]

## Copper Shield 66

# Alternate Brand Name: "CuVerrom",

\*NOTE: Product labels will bear the name of a copper alloy specified in the approved registration. Distributors may substitute a Product Brand Name in place of the name of the copper alloy on the label.

Active Ingredient:

Copper

66.5%#

Other

33.5%\*

\* 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%

EPA Registration No. \*\*\*\*
EPA Establishment No. \*\*\*\*\*

Made in the United States by \*\*\*\*\*\*\*

Distributed by \*\*\*\*\*\*\*\*

Net Contents: \*\*\*\*\*

[Back panel]

Laboratory testing has shown that when cleaned regularly:

[This [product] [surface] continuously reduces bacterial\* contamination, achieving 99.9% reduction within two hours of exposure.]

[This [product] surface kills greater than 99.9% of Gram-negative and Gram-positive bacteria\* within two hours of exposure.]

[This [product] surface delivers 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, this [product] surface kills greater than 99.9% of bacteria\* within two hours, and continues to kill more than 99% of bacteria\* even after repeated contamination.]

[This [product] surfaces help inhibit the buildup and growth of bacteria\* within two hours of exposure between routine cleaning and sanitizing steps.]

\* 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 a copper 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. The copper surface material has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

**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 use 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 pesticidal claims will be made as part of these materials.]

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Proper Care and Use [of Copper Shield 66]: The use of [antimicrobial copper surfaces] [this surface] does not replace standard infection control procedures and good hygienic practices. Surface[s] 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.

Surface[s] 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 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 surface. Cleaning agents typically used for traditional touch [hard] 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 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.

[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.] [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**

- o Bedrails, footboards
- 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
- O 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)

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- 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
- 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
- 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
- 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)
- o Floor tiles
- o 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

- 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 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.
- 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,
- o 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
- 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)
- 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)

- 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
- 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 (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)
- 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

#### Other

 Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring

#### STORAGE AND DISPOSAL

Copper Shield 66 should be disposed in a responsible manner, including recycling.

#### WARRANTY STATEMENT

If used as intended, Copper Shield 66 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.

### **Optional Label Claims:**

### [Residential]

- Kills 99.9% of Staphylococcus aureus, Escherichia coli O157:H7, and Pseudomonas aeruginosa.
- This product kills \*bacteria continuously.
- Kills bacteria continuously
- This product inhibits the growth of Staphylococcus aureus, Escherichia coli O157:H7, and Pseudomonas aeruginosa on its surface.
- Continuously kills bacteria on its surface
- Continuously reduces bacterial contamination
- Kills/eliminates/reduces germs/bacteria left behind (by dirty hands)
- Works even when you're sleeping.
- Provides On-Going Protection
- Continues to reduce/kill bacteria even when you don't have time to clean/disinfect
  - \* Testing demonstrates effective antibacterial activity against Staphylococcus aureus, Escherichia coli O157:H7, and Pseudomonas aeruginosa.

#### [Industrial and Commercial]

- Kills 99.9% of Staphylococcus aureus, Enterobacter aerogenes, Methicillin-Resistant Staphylococcus aureus (MRSA), Escherichia coli O157:H7, and Pseudomonas aeruginosa.
- Kills \*bacteria continuously.
- Inhibits the growth of Staphylococcus aureus, Enterobacter aerogenes, Methiciliin-Resistant Staphylococcus aureus (MRSA), Escherichia coli O157:H7, and Pseudomonas aeruginosa on its surface.

- Continuously Reduces bacterial growth on this common touch surface
- Continuously kills bacteria left behind on this surface by users/the public/your customers.
  - \* Testing demonstrates effective antibacterial activity against Staphylococcus aureus, Enterobacter aerogenes, Methicillin-Resistant Staphylococcus aureus (MRSA), Escherichia coli O157:H7, and Pseudomonas aeruginosa.