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

NOV 6 2009



# United States Environmental Protection Agency Office of Pesticide Programs

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

Attention: Amy Plato Roberts

**Subject: Copper Shield 82** 

EPA Registration No. 85353-3 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™ III "

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

Marthe Lany / 300

Product Manager (33)

Regulatory Management Branch 1

Antimicrobials Division (7510P)

Please read instructions on	reversa before completi	na form.	<del> </del>	Form /	pproved	, OMB No.	2070-00	80. Approval expires 2-28-95	
United States Environmental Protecti Washington, DC 20			tion Agency			Registre Amend Other		OPP Identifier Number	
Application for Pesticide - Section I									
1. Company/Product Number 85353-3			EPA Product Manager     Marshall Swindell			<u> </u>	3. F	Proposed Classification  None Restricted	
4. Compeny/Product (Name) Copper Shield 82				PM# 33					
5. Name and Address of Applicant (Include ZIP Code) Global Brass and Copper Inc. 427 North Shamrock Street East Alton, IL 62024  Check if this is a new address			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.						
			Section	oduct Name					
Amendment - Explain below.  Resubmission in response to Agency letter dated  Notification - Explain balow.				Final printed labels in repsonse to Agency letter dated "Me Too" Application. Other - Explain below.					
Explanation: Use addition Label notification to add an A This notification is consistent labeling or the confidential st to EPA. I further understand FIFRA and I may be subject	Atternate Brand Name. So with the provisions of PF atement of formula for thi that if this notification is r	ee attached R Notice 98-1 is product. I not consister	cover letter dated 0 and EPA regul understand that it with the terms	d October 8, 200 dations at 40 CF it is a violation of of PR Notice 98	R 152.46 of 18 U.S. I-10 and	3, and no othe .C. Sec. 100	to willfull	v make anv false statement	
		•	Section	- 111					
1. Material This Product Wi	Be Peckeged in:								
Child-Resistant Packaging Yes No Cartification must be submitted	Yes No No H "Yes" Unit Packeging wgt. No. per container			Water Soluble Packaging  Yes No If "Yes" Package wgt No. per container			2. Type of Container  Metal Plastic Glass Paper Other (Specify)		
3. Location of Net Contents Information 4. Size(s) Re			tall Container 5. Location of Label				oal Directi	ons	
Container  6. Manner in Which Label is Affixed to Product  Litho		graph Other			On Label				
,	Paper glued Steneiled								
			Section	- IV			<del></del>		
1. Contact Point (Complete	items directly below for	r identificatio	on of individual	to be contacted	d, if nece	essary, to pr	ocess this	epplication.)	
Name Amy Plato Roberts / aroberts@tsgusa.com			1			-	elephone No්(ලදාම්ල Area Code) 202) 828-8964		
	ation all attachments thereto are true, accurate and complete, tement may be punishable by fine or imprisonment or					8. Date Application Received			
2. Signature			3. Title Regulatory Consultant					, , , , , , , , , , , , , , , , , , ,	
4. Typed Name Amy Plato Roberts			5. Data October 8, 2009					, , , , , , , , , , , , , , , , , , ,	



#### WASHINGTON

1150 18th Street, N.W.

**Suite 1000** 

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 82; EPA Reg. No. 85353-3

### Label NOTIFICATION to add an alternate brand name

#### **SACRAMENTO**

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

Dear Mr. Swindell:

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 above referenced product:

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;

1) Notification form;

hbjornson@tsqusa.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™III,"

#### CANADA

275 Slater Street

Suite 900

35.10 30

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 82

# Alternate Brand Name: "CuVerrom" III,

\*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 82.6%\*
Other 17.4%\*
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. \*\*\*\*\*
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] surface helps 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.]

Proper Care and Use of Copper Shield 82: The use of [antimicrobial copper surfaces] [this surface] does not replace standard infection control procedures and good hygienic

Global Brass and Copper Inc.: Copper Shield \$2 Label NOTIFICATION to add an alternate brand name Label version (2) dated October \$3,2009 Page 2 of 8 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
- 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)	ეისიიი ე ჭ
Computer carts	9
Record carts	0000
Phlebotomy carts	٥
Other Carts (tables/surfaces, shelving, railings, handles, pulls)	, , , , , , , , , , , , , , , , , , , ,
ment carts (horizontal surfaces, frames, handles)	3193
,	3 2 3

- 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
- 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, tape@ed.andball 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

- 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
- 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
- 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)

- O 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)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- o Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- Soap dispenser (wall mounted): push bar and dispenser itself
- O Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- 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)
- Single and double-hung windows (locks and pulls)
- Light switches, switch plates
- o Lids of laundry hampers, trash canisters, and other containers

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

- O 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
- 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

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

# STORAGE AND DISPOSAL

Copper Shield 82 should be disposed in a responsible manner, including recycling.

### WARRANTY STATEMENT

If used as intended, Copper Shield 82 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.

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# **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, Methicillin-Resistant Staphylococcus aureus (MRSA), Escherichia coli O157:H7, and Pseudognonas 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.

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