82012-6

3/21/2013

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

#### **EPA** United States Environmental Protection Office of Pesticide Programs

Copper Development Association 260 Madison Avenue New York, NY 10016 MAR 2 T 2013

Attention: Joseph J. Green

Subject: ANTIMICROBIAL COPPER ALLOYS-GROUP VI EPA Registration No: 82012-6 Notification Dated: February 15, 2013

This will acknowledge receipt of your notification, submitted under the provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 3(c) (9).

#### Proposed Notification

- To add additional new use sites on the product label

#### General Comments

Base on a review of the submitted material, the following comments apply:

The Notification dated February 15, 2013, is compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Zebora Johnson at (703) 308-7080.

Sincerely

Marshall Swindell Product Manger (33) Regulatory Management Branch I Antimicrobial's Division (7501P)

Please read instructions of	n reverse before con	ting form.		Form Appro	ved	MB No. 207	0-0060	Print Form		
United States Environmental Protecti Washington, DC 20		United States	on Agency		<u> </u>	Registration Amendment Other		OPP Identifier Number		
		Application	n for Pestici	de - Sect	ion	l	****	. <b>1</b>		
1. Company/Product Number 82012-6			2. EPA Product Manager Marshall Swindell				3. Pr	3. Proposed Classification		
4. Company/Product (Name) Antimicrobial Copper Alloys Group√l			<b>PM#</b> 33				<u>ר</u> ר	None Restricted		
5. Name and Address of Copper Developmen 260 Madison Avenue	odej	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.								
Check if t	his is a new address		Produ	ct Name _	·					
			Section - I	1						
Amendment - Exp Resubmission in r Notification - Expl	[] []	Final printed labels in response to Agency letter dated "Me Too" Application. Other - Explain below.								
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1. Material This Product								<u> </u>		
* Certification must be submitted	X     No       X     No       Visit Packaging wat     No. per container		Water Soluble Packaging Yes No If "Yes" No. per Package wgt container			2. Type of Container Metal Plastic Glass Paper X Other (Specify) None				
3. Location of Net Contents Information 4. Size(s) Reta						ation of Label Directions				
Label     Label     Manner in Which Label	Container	Lithogra Paper gl Stencile	ph	X Other	AHY	oded to Billig				
	<u></u>		Section - I	V			<u>с с</u> сс	6 6 6 6 6 6		
1. Contact Point /Comple	ete items directly below	for identification	of individual to b	e contacted, i	f nece	ssary, to proc	ess this	application.)		
Name Joseph J. Green			Title Counsel to CDA		۲ ۲	ິ່ງ ອີຣິຣິກິດາອ No. (Include Area 202.342.8849ະ ັິັັັັັັັັັັັັັັັັັັັັັັັັັັັັັັັັັັັ				
	ataments I have made or any knowingly false or r ile law.		I attachments the					6. Dete Application Received (Stamped)		
2. Signature			. Title Counsel to Copper Development Assoc.							
4. Typed Name Joseph J. Green			. Date February 15, 20	13						

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

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# ANTIMICROBIAL COPPER ALLOYS GROUP VI AND ASSOCIATED FABRICATED PRODUCTS MASTER LABEL

The Master Label consists of the label that will accompany the Antimicrobial Alloys and a label that will accompany each product fabricated using a registered alloy from Antimicrobial Copper Alloys Group VI.

[Alloy Label – Front Panel]

## ANTIMICROBIAL COPPER ALLOYS GROUP VI AND ASSOCIATED FABRICATED PRODUCTS

Active Ingredient: Copper Other

62.0% ~ 38.0%

Total

100%

EPA Registration No. 82012-6 EPA Establishment No. \*\*\*\*\* Made in the United States by \*\*\*\*\*\* Distributed by \*\*\*\*\*\*

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Net Weight: XXX lbs XXX ounces of [brand name]



#### **DIRECTIONS FOR USE**

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

#### Antimicrobial Copper Alloys Group VI

These alloys are 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 Antimicrobial Copper Alloys Group VI and fabricated products made from Antimicrobial Copper Alloys Group VI under EPA Registration Number 82012-6.]

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

#### **Touch Surface Components**

#### Healthcare Facilities

- o Bedrails, footboards
- o 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)
- o 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
- o 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

- 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
- 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
- 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)
- 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, c, c
   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

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

#### *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
- o 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
- o Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- o 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)
- o Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- o Jalousie Windows (crank)
- o Casement (cranks, levers, hinges)

o Light switches, switch plates

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

o Magazine rack

- o Signage
- o Coat rack and hooks
- o Shower curtain rings
- o Radiator cover
- o Bracelets
- o Badge clips
- o Name tags
- Vending machines (non-food contact only)
- o Window sills
- o Electrical wallplates
- o Clip boards
- o 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
- o Door push plates
- Sinks: spigots, drains, sinks themselves
- o Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- o Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- o Towel bars
- o Showerheads
- 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
- Toilet seat inlay for lifting of seat
- o Light switches, switch plates
- Thermostat covers, control knobs and wheels
- o Telephone handsets and surfaces (housings), keypad
- o Floor tiles
- 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

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• 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
- o Bedside pitchers
- Closet rods and hangers
- o Television remote
- o Cup Holder
- Toothbrush holder
- o Soap holder, dispenser
- o Magazine rack
- o Coat rack and hooks
- Shower curtain rings
- o Radiator cover
- o Window sills
- o Electrical wallplates
- o Baby cribs: rails, fittings, brackets, supports
- o Bowl stands
- o Office supplies: paper clips, staplers, tape dispensers
- o Monitor (television, computer, etc.) housing

#### Mass Transit Facilities

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

#### Laboratories

- Incubator interior and outside surfaces, including culture chambers, walls, construction in the surfaces, including fan assemblies, pen includi
- o Laboratory surfaces: table tops, counter tops, handles, cabinet doors, cabinet
- o Laboratory carts, trays, and pans
- o Door handles, knobs, latches and locks
- o 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

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- o Chapel pews
- o Eye glass frames and protective eye wear
- o Pens
- o Combs
- o Ashtrays

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

#### Antimicrobial Copper Alloys Group VI – Fabricated Products

The Antimicrobial Copper Alloys Group VI fabricated products listed above may be sold and distributed under EPA Registration Number 82012-6. Products fabricated with Antimicrobial Copper Alloys Group VI 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.

### ANTIMICROBIAL COPPER ALLOYS GROUP VI Fabricated Product Label

#### FRONT

## [This (touch surface) (product)] made from Antimicrobial Copper Alloys Group VI Active Ingredient:

Copper.	62.0%
Other	
[Total	100.0%]
See [Back/Sid	de Panel][Insert] for Directions for
Use	
Net Weight: 2	XXX lbs XXX ounces of [brand
name]	-

#### BACK

#### ANTIMICROBIAL COPPER ALLOYS GROUP VI

- Laboratory testing has shown that when cleaned regularly this surface:
  Continuously reduces bacteria\* 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 touck 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. cc

[Items exposed to outdoor environmental conditions are not representative of indoor laboratory test conditions, and, therefole, 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. 82012-6 EPA Est. No. [Product Manufacturer Number] 82012-NY-001							2012-NY-001	
Manufactured by: [Product Manufacturer Company Name and Address]								
Copper	Development	Association,	260	Madison	Ave.,	NY,	NY	10016-240

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