9/30/2013



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

SEP 30 2013

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mr. Micah T. Reynolds c/o Hussey Copper Technologies Sciences Group, Inc. 1150 18th Street, Suite 1000 Washington, D.C. 20036

Subject: MD-CU₂₉ 3

EPA Registration Number 89187-3 Your Notification Dated September 9, 2013 EPA Received Date September 11, 2013

The notification referred to above, submitted in connection with the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to update and add the website address to the product labeling, is acceptable.

The language on the product's website has been revised. It does not show any unsupported efficacy claims. All unacceptable claims have been removed from the company's website.

This notification has been made a permanent part of this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

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

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Please read instructions	on reverse side before completin	na form	For	n Annrovec	OMB No 2070-0	060. Approval expires 05-31-98	
\$EPA	EPA United States ENVironmental Protection Washington, DC 20460			Re	egistration mendment ther	OPP Identifier Number	
		Applicat	ion for Pesticide – Se	ection I			
1. Company/Product Number 89187-3			Marshall S	2. EPA Product Manager Marshall Swindell		. Proposed Classification	
4. Company/Product MD-CU ₂₉ 3	(Name)		PM# 33				
5. Name And Addres Libertas Cop 100 Washing Leetsdale, Pe	s Of Applicant <i>(Include ZIP C</i> per LLC dba Huss ton Street annsylvania 15056 if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)					
			Section II		<u> </u>		
Amendment – E Resubmission in Notification – E	n response to Agency letter d	Agency le	 Final Printed labels in response to Agency letter dated "Me Too" Application. Other – Explain Below. 				
to EPA. I further und of FIFRA and I may b	erstand that if this notificatior e subject to enforcement act	is not consistent ion and penalti	ent with the terms of PR Notice ies under sections 12 and 14 o reynolds@tsgusa.com, Section III	e 98-10 and f FIFRA.	40 CFR 152.46, th		
1. Material This Produ	uct Will Be Packaged In:						
Child Resistant Pack	Yes No	No. per Container		o. per ontainer	2. Type of Conta Metal Plastic Glass Paper	;	
3. Location of Net Co	ntents Information	4. Size(S) R	etail Container	5.	Location of Label D		
6. Manner in Which L	abel is Affixed to Product	Lithogra	lued L	Other			
			Section IV				
1. Contact Point (Con	nplete items directly below fo	r identification	of individual to be contacted, il	necessary			
Name Micah T. Reynolds, Technology Sciences Group, Inc.			Title Senior Regulatory Consu				
I acknowled	t the statements I have made lge that any knowingly false applicable law.	Certifica on this form a or misleading s	ition nd all attachments thereto are statement may be punishable b	true, accur by fine or im	ate and complete.	c6. Date Application Receiveo ເຼິ (Stainoed)	
2. Signature Micart Row			3. Title Regulatory Consultant to Hussey Copper Ltd.				
4. Typed Name A Solution Micah T. Reynolds			Date September 9, 2013				

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



Technology Sciences Group Inc.

Mr. Marshall Swindell, PM-33 Antimicrobials Division (7510P) Office of Pesticide Programs

U.S. Environmental Protection Agency Document Processing Center (NOTIF) Room S-4900, One Potomac Yard

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

September 9, 2013

Hussey Copper		(((() ((()
MD-CU ₂₉ 3, EPA Reg. No. Label Notification	2 7 7 2 3 7 2 7 2 7 7 7 7 7 7 7 7 7 7 7 7 7 7	
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Dear Mr. Swindell:

2777 South Crystal Drive Arlington, Virginia 22202

Technology Sciences Group, Inc., on behalf of Libertas Copper, LLC dba Hussey Copper, 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 (82012-4); 2) add optional marketing statements consistent with existing label claims and statements; 3) add a new company logo; 4) add a website reference; 5) add optional text to the warranty statement; and 6) add text to identify the various finishes of the copper product. It is important to identify that the company website is not currently active (reflected as "Under Construction") until such time as statements, claims, and scope of advertising are fully addressed by the Copper Development Association and the Agency. Please find enclosed the following documents supporting this notification:

- 1) EPA Notification Form (EPA Form 8570-1);
- 2) One (1) copy of the product labeling with changes highlighted;
- 3) Three (3) copies of the revised product label.

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 <u>mreynolds@tsgusa.com</u>.

Sincerely,

Regulatory Consultant to Hussey Copper

Enclosures CC: C. Acors, J. Linton, J. Chi (Hussey Copper)

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

MD-CU₂₉ 3 ANTIMICROBIAL COPPER ALLOYS 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 $MD-CU_{29}$ 3.

[Alloy Label – Front Panel]

MD-CU₂₉ 3 AND ASSOCIATED FABRICATED PRODUCTS

Active Ingredient: Copper Other

73.0% 27.0%

Total

100%

EPA Registration No. 89187-3 EPA Establishment No. ***** Made in the United States by Hussey Copper 100 Washington Street Leetsdale, Pennsylvania 15056

Net Weight: XXX lbs XXX ounces of MD-CU₂₉ 3

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DIRECTIONS FOR USE

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

<u>MD-CU₂₉ 3</u>

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 MD-CU₂₉ 3 Antimicrobial Copper Alloys and fabricated products made from MD-CU₂₉ 3 under EPA Registration Number 89187-3.]

A list of components that may be fabricated out of MD-CU₂₉ 3 Antimicrobial Copper Alloys is specified below. MD-CU₂₉ 3 Alloys are not approved for direct food contact or food packaging uses.

Touch Surface Components

Healthcare Facilities

- o 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
- o Bedrails, assistance rails,
- Toilet safety rails
- o Carts
- Hospital carts (table surfaces, handles, legs) Computer carts
- Record carts
- Phlebotomy carts
- Other Carts (tables
- 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
- 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)

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- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Panic bars on emergency room doors
- Towel bars

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- Showerheads
- Countertops and tabletops (non-food use only)
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- o Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- \circ Closures
- Vertical locking arms
- Vertical cover guards
- o Protection bars
- Light switches, switch plates
- o Visitor chairs: armrests, metal frames
- o 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)
- o Floor tiles
- Ceiling tiles (non-porous)
- 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

• 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
- 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
- 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; kinges)
- Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting code units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV

- 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
- o 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
- Bedside pitchers
- o Closet rods and hangers.
- o Television controls: knobs, buttons, remote
- o Monitor (television, computer, etc.) housing
- o Cup Holder
- Toothbrush holder
- o Soap holder, dispenser
- o Magazine rack
- o Signage
- o Coat rack and hooks
- 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

Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- ATM machines: keys, housing
- o 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

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- Toilet paper dispenser (housing)
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- o Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)

- 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
- Name tags
- Vending machines (non-food contact only)
- 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
- \circ Handrails
- o Stair rails
- o Door push plates
- Sinks: spigots, drains, sinks themselves
- o Faucet: handles, spigot, drain control lever
- o Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- o Showerheads
- Countertops and tabletops
- Hinges, locks, latches, and trim
- o Door stops, door pulls, and protector guards
- 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
- Telephone handsets and surfaces (housings), keypad
- o Floor tiles
- Ceiling tiles (non-porous)
- o 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),

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Jalousie Windows (crank)

• Casement (cranks, levers, hinges)

- Single and double-hung windows (locks and pulls)
- o Television control knobs and buttons
- o Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- o Closet rods and hangers
- Television remote
- o Cup Holder
- o Toothbrush holder
- o Soap holder, dispenser
- o Magazine rack
- Coat rack and hooks
- o Shower curtain rings
- Radiator cover
- o Window sills
- Electrical wallplates
- o Baby cribs: rails, fittings, brackets, supports
- Bowl stands
- 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
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- o Grab bars and handles
- Tiles: wall, floor, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- o 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
- o 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

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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.

<u>MD-CU₂₉ 3 – Fabricated Products</u>

The MD-CU₂₉ 3 fabricated products listed above may be sold and distributed under EPA Registration Number 89187-3. Products fabricated with MD-CU₂₉ 3 must bear the EPA approved fabricated product label [below] with one or more of the listed claims.

STORAGE AND DISPOSAL

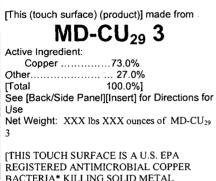
Dispose of excess by recycling.

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.

MD-CU₂₉ 3 **Fabricated Product Label**

FRONT



BACTERIA* KILLING SOLID METAL PRODUCT (WITH SWITCH COVER)]

(BRUSHED NICKEL FINISH) (BRUSHED NICKEL) (COPPER NICKEL)

BACK

This product is made of MD-CU₂₉ 3 antimicrobial copper.

- Laboratory testing has shown that when cleaned regularly this surface:
- [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.]
- [This product/product name] [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.] [If product is defective, contact Hussey Copper at the address below for return authorization guidelines.]

[For more available products and to learn more about MD-Gu29 scan the code with your smart phone] [www.md-cu29.com] [Patent Pendi(ig)C

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EPA Reg. No. 89187-3 EPA Est. No. [Product Monufacturer Number] 49187-XX-XXX Manufactured by: [Product Manufacturer Company Name and Address] Hussey Copper, 100 Washington Street, Leetsdale, Pennsylvania (5056

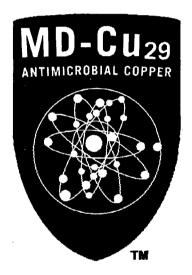
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MD-CU₂₉ 3 (EPA Reg. No. 89187-3) Master Label version dated September 9, 2013

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

Antimicrobial Copper





Made In [the] U.S.A [American Flag image] [QR code] [Images of product placement and/or installation/instructions]



