

89187-4

9/30/2013

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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 4
EPA Registration Number 89187-4
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,

A handwritten signature in black ink that reads "Marshall Swindell".

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

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Please read instructions on reverse side before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

	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 89187-4	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) MD-CU₂₉ 4	PM# 33	
5. Name And Address Of Applicant (Include ZIP Code) Libertas Copper LLC dba Hussey Copper 100 Washington Street Leetsdale, Pennsylvania 15056		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 _____
<input type="checkbox"/> Check if this is a new address		

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 optional marketing text, logos, and update non-food use sites.

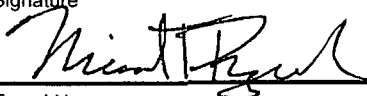
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false 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@tsgusa.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" No. per Unit Packaging wgt. Container	If "Yes" No. per Unit Packaging wgt. 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 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"/> Pager 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 Senior Regulatory Consultant	Telephone No. (Include Area Code) (202) 628-6567
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 Hussey Copper Ltd.		
4. Typed Name Micah T. Reynolds		5. Date September 9, 2013



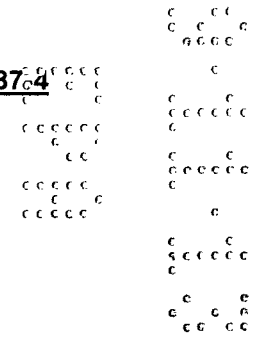
Technology Sciences Group Inc.
1150 18th Street, Suite 1000
Washington, DC 20036
Direct: (202) 828-8967
Fax: (202) 872-0745
E-Mail: MReynolds@TSGUSA.com

Micah T. Reynolds
Senior Regulatory Consultant

September 9, 2013

Hussey Copper
MD-CU₂₉ 4, EPA Reg. No. 89187-4
Label Notification

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
2777 South Crystal Drive
Arlington, Virginia 22202



Dear Mr. Swindell:

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 (82012-5); 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 mreynolds@tsgusa.com.

Sincerely,

Regulatory Consultant to Hussey Copper

Enclosures

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

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MD-CU₂₉ 4
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-CU₂₉ 4.

[Alloy Label – Front Panel]

MD-CU₂₉ 4
AND ASSOCIATED FABRICATED PRODUCTS

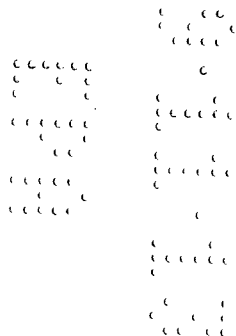
Active Ingredient:

Copper	66.5%
Other	33.5%
Total	100%

EPA Registration No. 89187-4
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 4



DIRECTIONS FOR USE

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

MD-CU₂₉ 4

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 4 Antimicrobial Copper Alloys and fabricated products made from MD-CU₂₉ 4 under EPA Registration Number 89187-4.]

A list of components that may be fabricated out of MD-CU₂₉ 4 Antimicrobial Copper Alloys is specified below. MD-CU₂₉ 4 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

- 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

- 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, dispenser
- 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,
- 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
- 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
- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Badge clips
- Name tags
- Vending machines (non-food contact only)
- Window sills
- Electrical wallplates
- Clip boards
- 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)
- Bedrails, footboards
- Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Showerheads
- Countertops and tabletops
- 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
- Light switches, switch plates
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Ceiling tiles (non-porous)
- 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)

- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television remote
- Cup Holder
- Toothbrush holder
- Soap holder, dispenser
- Magazine rack
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Window sills
- Electrical wallplates
- Baby cribs: rails, fittings, brackets, supports
- Bowl stands
- Office supplies: paper clips, staplers, tape dispensers
- Monitor (television, computer, etc.) housing

Mass Transit Facilities

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

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- Eye glass frames and protective eye wear
- Pens
- Combs
- Ashtrays

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

MD-CU₂₉ 4 – Fabricated Products

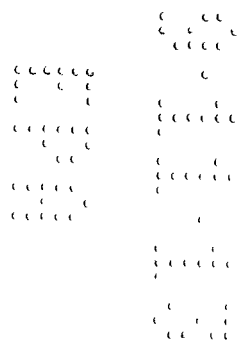
The MD-CU₂₉ 4 fabricated products listed above may be sold and distributed under EPA Registration Number 89187-4. Products fabricated with MD-CU₂₉ 4 must bear the EPA approved fabricated product label [below] with one or more of the listed claims.

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 4

Fabricated Product Label

FRONT

[This (touch surface) (product)] made from

MD-CU₂₉ 4

Active Ingredient:

Copper	66.5%
Other	33.5%
[Total	100.0%

See [Back/Side Panel][Insert] for Directions for Use

Net Weight: XXX lbs XXX ounces of MD-CU₂₉ 4

[THIS TOUCH SURFACE IS A U.S. EPA REGISTERED ANTIMICROBIAL COPPER BACTERIA* KILLING SOLID METAL PRODUCT (WITH SWITCH COVER)]

[(POLISHED BRASS FINISH) (POLISHED BRASS) (BRASS)]

BACK

This product is made of MD-CU₂₉ 4 antimicrobial copper.

Laboratory testing has shown that when cleaned regularly this surface:

- [This product] [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-CU₂₉ scan the code with your smart phone] [www.md-cu29.com] [Patent Pending]

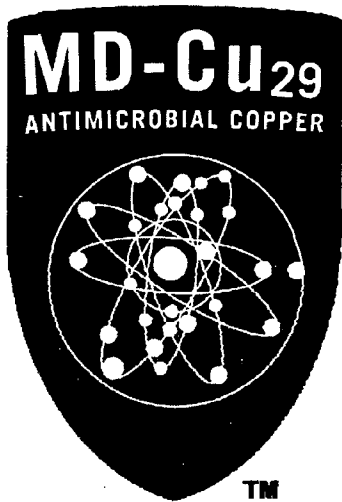
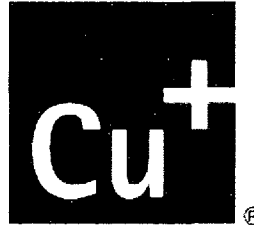
EPA Reg. No. 89187-4 EPA Est. No. [Product Manufacturer Number] 89187-XX-XXX
 Manufactured by: [Product Manufacturer Company Name and Address]
 Hussey Copper, 100 Washington Street, Leetsdale, Pennsylvania 15056

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MD-CU₂₉ 4 (EPA Reg. No. 89187-4)
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]

