

84542-7

09/11/2012

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**U.S. ENVIRONMENTAL PROTECTION AGENCY**

Office of Pesticide Programs  
Antimicrobials Division (7510P)  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460

EPA Reg. Number:  
84542-7

Date of Issuance:  
SEP 11 2012

Term of Issuance: **Conditional**

Name of Pesticide Product:  
Antimicrobial Cupron Enhanced  
EOS Surface

**NOTICE OF PESTICIDE:**  
 Registration  
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Cupron Technologies  
800 East Leigh Street  
Richmond, VA 23219

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product (OPP Decision Number: D-463794) is conditionally registered in accordance with FIFRA sec 3(c)(7)(B) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
  - a. Revise the EPA Registration Number to read, "EPA Reg. No. 84542-7".
  - b. Revise the last statement on page 2 and 7 by deleting the term, necessarily, such that the statement reads "... but it does not prevent cross contamination."

Signature of Approving Official:

Jacqueline Campbell-McFarlane, PM Team 34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Date:

SEP 11 2012

3. The following are a listing of Conditions of Registration for CUPRON ENHANCED EOS SURFACE registrations and associated labeling issues:

**Condition 1**

Cupron Technologies will prepare and implement an Antimicrobial Cupron Enhanced EOS Surface Stewardship Plan ("the Plan") designed to support the responsible use of antimicrobial copper products. The Plan will be submitted for EPA review and approval within two months after the registration date. If EPA determines at any time after 18 months following registration that the Plan is not being adequately or timely implemented or that implementation of the Plan is not effectively ensuring the proper sale, distribution, or use of antimicrobial copper alloy products, the registration may be automatically cancelled by the Agency by order with no opportunity for a hearing but only after notification to the Registrant and an opportunity to meet with the Director of the Office of Pesticide Programs.

The Plan will include, at a minimum, the following elements:

- (a) Outreach to the infection control community, including:
  - (i) A goal of educating and reinforcing, for infection control professionals and other product users, the proper use of Antimicrobial Cupron Enhanced EOS Surfaces.
  - (ii) Written (including electronic) communications directed to associations of infection control professionals, including at the least APIC, ASHES, and any other relevant organizations identified by CDA or EPA, and State Departments of Health.
  - (iii) Outreach communications will be sent within six months after the date of registration and within one year after the date of registration, and then annually thereafter on the anniversary of the date of the registration unless more frequent outreach is deemed necessary.
  - (iv) The content of the outreach communications will include statements explaining the registered claims and applications of Antimicrobial Cupron Enhanced EOS Surfaces, as well as their proper use. The communications also will inform the recipients about (1) Cupron Technologies (see below) and invite their participation; (2) other sources of information on Antimicrobial Cupron Enhanced EOS Surfaces, including the Stewardship Website (see below). Additional content of outreach efforts will be developed as part of the workgroup activities.
- (b) Development of a Stewardship Website ("the Website") under the auspices of Cupron Technologies.
  - (i) The Website will serve as a resource for conveying accurate information to the public about the efficacy and proper use of Antimicrobial Cupron Enhanced EOS Surfaces.

		CONCURRENCES			
SYMBOL	(ii)	The Website will include information on proper labeling and claims (including advertising); supporting science; applications; maintenance; and federal and state regulations and statutory requirements.			
SURNAME					
DATE					

- (iii) A question and answer or Frequently Asked Questions (FAQs) section will be incorporated to address common issues or questions raised with regard to Antimicrobial Cupron Enhanced EOS Surfaces.
  - (iv) The Website also will serve as a forum to correct any false or misleading third party statements or publications, including scientific papers, concerning Antimicrobial Cupron Enhanced EOS Surfaces. Any such false or misleading third party statements or publications will be corrected promptly after Cupron Technologies becomes aware of such and the responsive Website update will be incorporated promptly thereafter. Cupron Technologies shall inform EPA within 30 calendar days following its receipt of any such false or misleading third party statements or publications and at that same time provide the Agency with a copy of such statement or publication along with a hard copy of the Website entry correcting such statement or publication.
  - (v) Links will be arranged and established by Cupron Technologies between the Stewardship Website and the websites of appropriate infection control organizations, including but not limited to APIC and ASHES.
- (c) Establishment of an Antimicrobial Cupron Enhanced EOS Surface Working Group ("the Working Group").
- (i) Invited participants will include Cupron Technologies, component makers, and representatives from the infection control community, including appropriate trade associations (e.g., APIC and ASHES) and State Departments of Health.
  - (ii) The Working Group will meet at least twice a year, either in person or by live video conferencing (WEBEX) or teleconferencing.
  - (iii) The Working Group will serve as a forum to expand educational efforts, develop outreach communications, and address any questions or concerns from the public and infection control community.
  - (iv) Cupron Technologies shall provide EPA with minutes of any such meetings within 60 days of the end of any such meeting.

**Condition 2**

For at least the first 24 months after registration or until the Agency terminates this condition, whichever is later, the Cupron Technologies will submit to EPA sample advertising materials. Advertising materials will be representative of advertisements intended for use in the marketplace.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

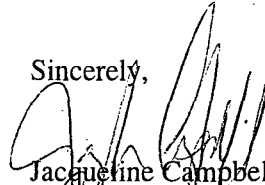
CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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EPA Reg. No. 84542-7  
Antimicrobial Cupron Enhanced EOS Surface

A stamped label with comments is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6416 or by email at [Campbell-mcfarlane.jacqueline@epa.gov](mailto:Campbell-mcfarlane.jacqueline@epa.gov) or Stacey Grigsby by telephone at (703) 305-6440 or [grigsby.stacey@epa.gov](mailto:grigsby.stacey@epa.gov) during the hours of 8:30 am to 4:00 pm EST.

Sincerely,



Jacqueline Campbell,  
Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Enclosures: (Stamped Label)

<b>Master Label containing</b> <b>Sublabel 1. Complete Label</b> <b>Sublabel 2. Hang Tag label</b>
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Sublabel I. Complete Label

## Antimicrobial Cupron Enhanced EOS Surface

Ingredients	
Copper (I) Oxide	16.0%
Other Ingredients	84.0 %
Total	100 %

EPA Registration No. 84542-7

EPA Establishment No

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

Manufactured by  
 Cupron Technologies  
 800 East Leigh St  
 Richmond VA 23219

ACCEPTED  
 with COMMENTS  
 in EPA Letter Dated:

SEP 11 2012

Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act as  
 amended, for the pesticide,  
 registered under EPA Reg. No.

84542-7

Label may contain 1 or more of the statements listed below in [ ]

## Antimicrobial Cupron Enhanced EOS Surface

Laboratory testing has shown that when cleaned regularly:

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

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

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

[This 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* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), Methicillin-Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* 0157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442).

The use of an Antimicrobial Cupron Enhanced EOS 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 Antimicrobial Cupron Enhanced EOS Surface has been shown to reduce microbial contamination but it does not ~~necessarily~~ prevent cross contamination.

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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.

[The directions in bracketed text 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]

**Proper Care and Use of Antimicrobial Cupron Enhanced EOS Surfaces:**

**The use of Antimicrobial Cupron Enhanced Hard Surfaces does not replace standard infection control procedures and good hygienic practices. Antimicrobial Cupron Enhanced Hard Surfaces 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.

Antimicrobial Cupron Enhanced EOS Surfaces 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 antimicrobial Cupron Enhanced EOS 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 Cupron Enhanced EOS Surface. Cleaning agents typically used for traditional touching surfaces are permissible; the appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. [Normal tarnishing or wear of the Antimicrobial Cupron Enhanced EOS Surface will not impair the antibacterial effectiveness of the product].

**This product must not be used on any direct food contact or food packaging uses.**

[Antimicrobial Cupron Enhanced EOS Surfaces 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 conditions, and therefore, may impart reduced efficacy if not cleaned when visibly soiled.]

**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 treads, 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)
- Doors, Door push plates, kick plates, mop plates, stretcher plates
- Sinks , drains, one piece sinks
- Paper towel holders, facial tissue holders, toilet paper holders
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surface)
- Panic bars on emergency room doors
- Towel bars
- Countertops and tabletops (non-food contact surface use only)
- Door stops, door pulls and protector guards
- Light switches, switch plates
- Kitchen surfaces (non food contact surfaces only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, controls knobs (appliances, fans)
- Floor tiles
- Ceiling tiles
- Wall decorative tiles
- Instrument casing and molded knobs, pulls and 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

- Trays (instruments, non food contact only)
- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs frame or chair hard surface (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Headwall systems: the unit themselves, outlet covers, monitor housings, knobs, baskets, tables
- Critical care cart: Table top, drawer
- Toilet seat, toilet seat cover, door and cabinet facings, counter tops
- Storage Shelving: wire shelving etc for medical supplies
- Grab handles on privacy curtains
- laundry hampers, trash canisters, and other containers
- Window sills,
- Electrical wall plates

***Community Facilities (including various public and commercial buildings):***

- Shopping carts, child seats, handrails
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Elevator: handrail, control panels, interior walls, floor tiles, exterior call button plate
- Toilet paper dispenser (housing)
- Windows (crank)
- Light switches, switch plates
- laundry hampers, trash canisters, and other containers
- Window sills
- Electrical wall plates

***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 treads, stair rails
- Stair rails
- Door push plates, doors
- Sinks, drains, sinks themselves
- Door handles, doorknobs (outer touch surfaces)
- Towel bars
- Countertops and tabletops
- Light switches, switch plates

- Floor tiles
- Ceiling tiles
- Wall decorative tiles
- Exercise and gym equipment, handles, bars
- laundry hampers, trash canisters, and other containers
- Window sills
- Electrical wall plates

***Mass Transit Facilities***

- Wall panels
- Handrails
- Stair rails, stair treads, railing and supports; elbows and brackets
- Door push plate, 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

**STORAGE AND DISPOSAL**

ANTIMICROBIAL CUPRON ENHANCED EOS SURFACES should be disposed of in a responsible manner, including recycling.

**WARRANTY STATEMENT**

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Tree injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or tree conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of CUPRON LLC. or seller. To the extent consistent with applicable law, all such risks shall be assumed by Buyer and User, and Buyer and User agree to hold CUPRON INC. and seller harmless for any claims relating to such factors.

CUPRON INC. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions. This warranty does not extend to the use of the product contrary to label instructions, and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, CUPRON INC. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

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**Sublabel 2. Hang Tag**

**Antimicrobial Cupron Enhanced EOS Surface**

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