




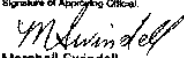
# Antimicrobial Copper is governed by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- Any product claiming to kill human pathogens (e.g. bacteria) is regulated as a pesticide in the US by EPA
- FIFRA functions:
  - Federal control of pesticide distribution, sale, and use
  - Assures that pesticides will be properly labeled
  - Pesticides will not cause unreasonable harm to humans or the environment



# U.S. EPA public health registration for solid, copper alloys (Antimicrobial Copper)

- Groundbreaking registration
- Claims against 6 deadly bacteria
- First class of solid surfaces to obtain this form of registration
- Previously reserved for liquid and aerosol disinfectants

 <p><b>U.S. ENVIRONMENTAL PROTECTION AGENCY</b> Office of Pesticide Programs Antimicrobials Division (7510C) 1200 Pennsylvania Avenue NW Washington, D.C. 20460</p> <p><b>NOTICE OF PESTICIDE:</b> <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration</p> <p><small>(under FIFRA, as amended)</small></p>	<p>EPA Reg. Number: 82012-1</p>	<p>Date of Issuance: 02 29 08</p>
	<p>Term of Issuance: Conditional</p> <p>Name of Pesticide Product: Antimicrobial Copper Alloys - Group I</p>	
<p>Name and Address of Registrant (Include ZIP Code): Copper Development Association 280 Madison Avenue New York, New York 10016-2401</p>		
<p><small>On the basis of information furnished by the registrant, the above named pesticide is hereby registered/re-registered under the Federal Insecticide, Fungicide and Rodenticide Act.</small></p> <p><small>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.</small></p> <p>This product is conditionally registered in accordance with FIFRA sec 3(e)(7)(B) provided that you:</p> <ol style="list-style-type: none"> <li>1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(e)(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.</li> <li>2. Make the labeling changes listed below before you release the product for shipment:             <ol style="list-style-type: none"> <li>a. Add the phrase: "EPA Registration Number 82012-1."</li> </ol> </li> </ol>		
<p>Signature of Approving Official:  Marshall Swindell Product Manager-33 Regulatory Management Branch I Antimicrobials Division (7510P)</p>	<p>Date: 02 29 08</p>	

EPA Form 8570-6

# EPA-registered public health claims for products made from Antimicrobial Copper

- 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 delivers continuous and ongoing antibacterial\* action, remaining effective in killing greater than 99.9% of bacteria\* within two hours.
- 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*, *Enterobacter aerogenes*, Methicillin-Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* 0157:H7, and *Pseudomonas aeruginosa*

# **EPA requires the following mandatory language to be clearly displayed on all marketing materials**

\*Laboratory testing shows that, when cleaned regularly, antimicrobial copper surfaces kill greater than 99.9% of the following bacteria within 2 hours of exposure: MRSA, VRE, *Staphylococcus aureus*, *Enterobacter aerogenes*, *Pseudomonas aeruginosa*, and *E. coli* O157:H7. Antimicrobial copper surfaces are a supplement to and not a substitute for standard infection control practices and have been shown to reduce microbial contamination, but do not necessarily prevent cross contamination or infections; users must continue to follow all current infection control practices.

# EPA requires the following messages to be clearly presented in all marketing materials



- Antimicrobial Copper needs to be seen as a supplement to, not a substitute for, standard infection control practices.
- One must continue to follow all current practices, including those practices related to cleaning and disinfection of environmental surfaces.
- Antimicrobial Copper alloy surfaces must not be waxed, painted, lacquered, varnished, or otherwise coated. The alloys tarnish to varying degrees, which does not impair their antimicrobial efficacy.

## Marketing boundaries set by EPA: Member registrants should not...

- Directly or indirectly imply that products made from Antimicrobial Copper alloys can reduce, control, prevent, or otherwise impact infections in hospitals or elsewhere
- **INCORRECT:** Incorporating Antimicrobial Copper surfaces into your hospital can help reduce healthcare-associated infections.
- **CORRECT:** Incorporating Antimicrobial Copper surfaces into your hospital can help reduce the bacteria\* that cause healthcare-associated infections
- The focus should always be on efficacy against the 6 registered bacteria that cause infections, not the infections themselves

## Marketing boundaries set by EPA: Member registrants should not...

- Directly or indirectly imply that products made from Antimicrobial Copper alloys can treat or prevent disease, illness, absenteeism, or improve public health and safety
- **INCORRECT:** Antimicrobial Copper surfaces can create a safer and healthier environment at your hospital.
- **CORRECT:** Antimicrobial Copper surfaces provide continuous protection against disease-causing bacteria\*
- **CORRECT:** Antimicrobial Copper surfaces are your new weapon in the fight against healthcare associated infections, killing greater than 99.9% of bacteria\* within 2 hours



## Marketing boundaries set by EPA: Member registrants should not...

- Directly or indirectly imply that products made from Antimicrobial Copper alloys can reduce, control, or prevent cross contamination or the “spread” of bacteria
- **INCORRECT:** Antimicrobial Copper surfaces can prevent the spread of bacteria in your facility.
- **CORRECT:** Antimicrobial Copper surfaces continuously kill greater than 99.9% of bacteria\* within 2 hours
- The continuous reduction label claims deliver a strong message without making direct or implied cross contamination claims

## Marketing boundaries set by EPA: Member registrants should not...

- Directly or indirectly imply that products made from Antimicrobial Copper alloys kill the 6 registered bacteria faster than 2 hours
- **INCORRECT:** Antimicrobial Copper surfaces kill greater than 99.9% of MRSA in minutes
- **CORRECT:** Antimicrobial Copper surfaces kill greater than 99.9% of MRSA within 2 hours
- The 2 hour contact time must be clearly noted when discussing kill times in all marketing collateral

# Marketing boundaries set by EPA: Member registrants should not...

- Directly or indirectly imply efficacy against viruses, fungi, bacteria or other microorganisms, that are not one of the six registered bacteria included in the current registrations
- This includes the promotion and dissemination of scientific studies reporting efficacy in laboratory, clinical or real world settings

# Phraseology EPA has objected to in the past

- “Naturally antimicrobial”
  - EPA argues that copper alloys are man processed, so the effect cannot be marketed as “natural”
  - “Inherently” or “intrinsically” antimicrobial are appropriate
- Any reference to efficacy against “germs”
  - “Germs” implies viruses and fungi, and only bacteria are registered
- Kills bacteria “on contact” or “immediately”
  - Implies an instant effect which EPA considers to be misleading
  - The 2 hour kill time must be clearly stated
- “Eliminates” bacteria
  - This implies an absolute effect that EPA deemed to be too strong

# The importance of complying with EPA marketing guidelines

- EPA levies significant fines for claim violations
  - 2008: EPA fined a manufacturer of computer keyboards with antimicrobial additives >\$200,000 for false claims
  - 2010: EPA fined a California company >\$500,000 for unsubstantiated antimicrobial claims for products containing silver-additives

# Marketing guidance resources

- EPA Label Review Manual provides specific examples and detailed guidance on acceptable label claims:
  - <https://www.epa.gov/sites/production/files/2015-03/documents/chap-12-nov-2013.pdf>