

Proper Use and Care of Antimicrobial Copper Alloys

(Updated 2016)

Background on the Registration of Antimicrobial Copper Alloys

In 2004, after preliminary laboratory research demonstrated that copper and certain copper alloys, such as brass and bronze, exhibit inherent antimicrobial properties, the Copper Development Association (“CDA”)¹ initiated a four-year effort to obtain an EPA registration under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) for Antimicrobial Copper Alloys. That effort included developing test protocols in cooperation with the U.S. Environmental Protection Agency (“EPA”) to demonstrate and quantify, under Good Laboratory Practice (“GLP”) conditions, the antimicrobial properties of copper and various copper-based alloys. That testing revealed that 355 copper alloys, each of which contains at least 60 percent copper, kill 99.9 percent or more of bacteria within two hours of contact, even after repeated contamination². Based on these test data, six different groups of copper alloys (based on six different ranges of copper content) were registered with EPA (EPA Reg. Nos. 82012-1 through 6).

As a condition of registration, CDA agreed with EPA that responsible stewardship of the products was necessary, particularly given the unique antimicrobial characteristics of copper alloys. In particular, it is important for users to understand that the registered copper alloys are a supplement to and not a substitute for standard infection control practices, and that all current infection control practices, including those related to cleaning and disinfection of environmental services, must continue to be followed. Antimicrobial Copper Alloys are intended to provide supplemental antimicrobial action between routine cleanings of environmental or touch surfaces in healthcare settings, as well as in public buildings and the home. For these reasons, the outreach program was developed to reinforce these messages and to ensure a proper understanding of the potential role copper alloys may play in an infection control program.

CDA has obtained antimicrobial product registrations in all 50 states, and several CDA member companies that produce brass, bronze, and other copper alloys have obtained their own identical registrations with EPA and the states. Products made from Antimicrobial Copper alloys are now on the market. Available products include IV poles, instrument tables, mayo stands, stretchers, railings, door hardware, cabinet hardware, work surfaces, carts, and more.

The following is a summary of the primary aspects of CDA’s outreach effort: (1) the approved claims and registered applications for Antimicrobial Copper Alloys; (2) the Stewardship Website; and (3) the Antimicrobial Copper Alloys Working Group. In addition, we provide a brief overview of how Antimicrobial Copper Alloy components may be marketed, including labeling requirements.

Appropriate Claims and Uses of Antimicrobial Copper Alloys

Antimicrobial Copper Alloys have been approved for use in a variety of non-food contact touch surfaces in

¹ CDA is a non-profit trade association that acts as the primary information, engineering, and market development services organization for the copper industry in the United States and, through affiliated organizations, worldwide. CDA membership is comprised of domestic and international copper producers (mining, smelting and refining) and fabricating companies (brass and wire mills and foundries) with business operations in North America. Associate membership is available to companies that support the copper industry.

² Tests were conducted at room temperature and under normal humidity conditions. The organisms tested were: *Staphylococcus aureus*, *Enterobacter aerogenes*, *Escherichia coli* O157:H7, *Pseudomonas aeruginosa*, Vancomycin Resistant *Enterococci* (VRE) and Methicillin-resistant *Staphylococcus aureus* (“MRSA”).

healthcare facilities and public, commercial, and residential buildings. A list of the approved applications in healthcare facilities is included in the appendix.

The EPA registration allows the registered copper alloys to be marketed with certain antibacterial claims³. The basic claim is that laboratory testing has shown that Antimicrobial Copper Alloys kill 99.9% or more of bacteria within two hours of exposure. In making these claims, to be consistent with the EPA-approved label and registration, marketers also must convey that regular cleaning to remove dirt and grime that could prevent contact with the copper alloy surface should be conducted to ensure antibacterial performance. Further, the following message must be conveyed:

The use of a copper alloy 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 copper alloy surface material has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

In addition, in order to be effective, the alloys must not be coated in any way and routine cleaning and sanitization practices must be followed.

Accordingly, Antimicrobial Copper Alloys are NOT designed to replace current cleaning and sanitization procedures. Rather, Antimicrobial Copper Alloy surfaces can help reduce levels of bacteria on environmental surfaces between regular cleaning and sanitization activities. It is imperative that routine cleaning and sanitization procedures continue to be implemented to reduce the potential for infection and to keep the Antimicrobial Copper Alloy surface free of dirt and grime that could prevent contact with the surface and inhibit antimicrobial performance⁴.

In summary, the infection control community should keep in mind the following important messages regarding the proper use and care of Antimicrobial Copper Alloys:

1. Antimicrobial Copper Alloys are a supplement to and not a substitute for standard infection control practices, and users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces.
2. Antimicrobial Copper Alloy surfaces have been shown to reduce microbial contamination, but do not necessarily prevent cross contamination.
3. Regular cleaning should be conducted to remove dirt and grime that could prevent contact with the Copper Alloy surface and inhibit antibacterial performance.
4. Antimicrobial Copper Alloys must not be coated in any way⁵.

Also, in response to questions raised by members of the infection control community, a clinical trial using Antimicrobial Copper Alloys was conducted at the following institutions:

³The EPA-approved label for Antimicrobial Copper Alloys Groups I – VI allows for the following antibacterial claims: “Laboratory testing has shown that when cleaned regularly (1) Antimicrobial Copper Alloys continuously reduce bacterial* contamination, achieving 99.9% reduction within two hours of exposure; (2) Antimicrobial Copper Alloys surfaces kill greater than 99.9% of Gram-negative and Gram-positive bacteria* within two hours of exposure; (3) Antimicrobial Copper Alloys surfaces deliver continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within two hours; (4) Antimicrobial Copper Alloys surfaces kill greater than 99.9% of bacteria* within two hours, and continue to kill 99% of bacteria* even after repeated contamination; and (5) Antimicrobial Copper Alloys surfaces help 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* O157:H7, Vancomycin Resistant Enterococci (VRE), and *Pseudomonas aeruginosa*.)

⁴Testing has shown that the alloys remain effective in killing over 99% of bacteria up until the point at which a visible grime or film (caused by the buildup of dead cells and other dirt) appears.

⁵Normal tarnishing or wear of Antimicrobial Copper Alloy surfaces will not impair the antibacterial effectiveness of the product.

- Memorial Sloan-Kettering Cancer Center (New York, NY)
- Medical University of South Carolina (Charleston, S.C.)
- Ralph H. Johnson Veteran's Administration Medical Center (Charleston, S.C.).

The goal of the trial was to determine whether the introduction of copper touch surfaces decreases the levels of potentially harmful microbes in the hospital environment, and to assess whether or not there is a corresponding reduction in nosocomial infections. The trial demonstrated that Antimicrobial Copper Alloy surfaces significantly reduced bioload in the clinical environment and can provide another tool in the fight to reduce infections. The trial was conducted through funding, authorized by Congress, from the U.S. Department of Defense under the aegis of the Telemedicine and Advanced Technologies Research Center ("TATRC").

Note on "Treated Article" Antimicrobial Products: Many common "antimicrobial" products are not required to seek EPA public-health product registration under what is known as the "treated articles" exemption. In contrast to Antimicrobial Copper Alloys, such "treated articles" (often containing low concentrations of silver or nano-silver particles) may not make "public health" claims and do not have to submit to EPA efficacy data for the product. Theoretically, "treated articles" only may make claims related to protection of the article itself against non-specific bacteria, mold, or mildew that can cause odors, deterioration, etc. Unfortunately, many of these products take advantage of ambiguous and inconsistent enforcement of the "treated articles" exemption, and make claims that, at minimum, imply efficacy against bacteria that has not been demonstrated through rigorous testing.

Stewardship Website

CDA has established a Stewardship Website to serve as an information clearinghouse and resource for conveying accurate information to the public and infection control community about the efficacy and proper use and care of Antimicrobial Copper Alloys. The website is available at the following internet address: www.AntimicrobialCopper.com.

The Website includes information related to:

1. The EPA registration and regulatory guidelines, including proper labeling and claims;
2. Supporting science and additional research information
3. Potential applications and uses; and
4. Maintenance and care.

In addition, the Website includes a "Frequently Asked Questions" section to address common issues or questions raised with regard to Antimicrobial Copper Alloys. This section includes further discussion of (a) the scope of claims that can be made under the EPA-approved label; (b) the supplemental nature of the products and the need to continue regular cleaning and sanitization regimens; (c) the role of copper alloy products in infection control programs (e.g., not shown to prevent cross-contamination, but only to help reduce microbial contamination in between regular cleanings); (d) the need to keep the surfaces clean in order to enable antibacterial efficacy; and (e) the requirement not to coat the products. Additional issues will be addressed as they arise.

The Website also serves as a forum to correct false or misleading statements or publications, including scientific papers, concerning Antimicrobial Copper Alloys. When any such false or misleading statements or publications are identified, CDA issues a letter requesting correction or removal of the offending statement and the Website is updated promptly to provide a public clarification of the issue.

Please check the Website for the most up-to-date information, including clarifications and frequent Q&A's, regarding the proper use of Antimicrobial Copper Alloys. If you have any questions or request for additional information, please do not hesitate to contact CDA. Finally, EPA has requested that CDA establish links between the Stewardship Website and the websites of appropriate infection control and healthcare environmental services professional organizations. CDA requests infection control and healthcare organizations, as well as State departments of health, to provide a link on your organization's website

to www.AntimicrobialCopper.com.

Antimicrobial Copper Alloys Working Group

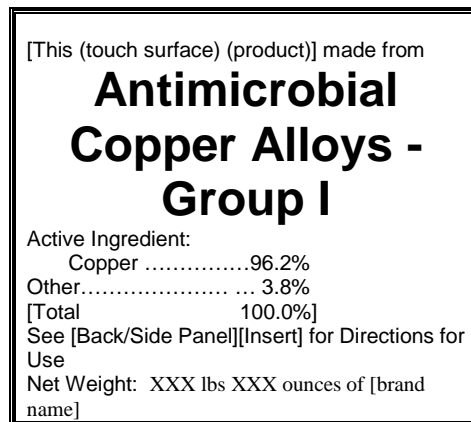
The Antimicrobial Copper Alloys Working Group is intended to serve as a forum to expand educational efforts, develop outreach communications, and address any questions or concerns from the public and infection control community. Participants include copper alloy manufacturers, component makers, and representatives from the infection control community, including ASHES and APIC, and State Departments of Health.

Working Group meetings will be conducted at least twice a year. It has been suggested that future meetings take place at or in conjunction with appropriate conferences or meetings of prominent infection control organizations. Please provide any suggestions regarding the timing and location of Working Group meetings. Further information on upcoming Working Group meetings will be provided to you. We encourage representatives from your organization to participate.

Marketing and Labeling of Antimicrobial Copper Alloys

CDA and its member companies have obtained the required federal and state registrations to enable the marketing of products (for the applications listed below) made from Antimicrobial Copper Alloys with public health claims. A variety of products (such as door knobs, handrails, push plates, and other touch surfaces) are available in the market made with Antimicrobial Copper Alloys. These products will bear a label, as required by federal and state regulations.

Antimicrobial Copper Alloy products will bear a “fabricated product label” type of label. This means that the front panel of the product packaging will bear a label that states that the product is “Made from” a particular brand name of Antimicrobial Copper Alloy (e.g., “Made from CuVerro® I, or Microguard”), as well as the ingredient statement identifying the percentage of copper in the product and a note directing the user to the Directions for Use on the back panel. An example is shown below.



The remaining antimicrobial labeling, including claims language, directions for use and registrant information, will appear on the back panel. The EPA registration number will be that of the manufacturer of the copper alloy that was used to create the retail component product. Additionally, the EPA facility number of the end-use product manufacturer will also be included.

For further information please contact:

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Appendix

List of Approved Applications for Antimicrobial Copper Alloys in 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
- 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