

[DATE]

[CONTACT INFO]

Dear XXXXX,

I am contacting you on behalf of the North American Copper Development Association (CDA) in response to the copper alloy-based products manufactured by [COMPANY] that are advertised with antimicrobial effectiveness claims. Representative product claims are enclosed with this letter in the appendix. CDA is issuing this communication to comply with our U.S. Environmental Protection Agency (EPA) mandated Stewardship Program established to protect consumers and educate the marketplace about the proper use and care of copper alloy materials used for antimicrobial public health applications.

As part of CDA's Stewardship responsibilities, we may inform EPA of this communication and post a summary on our Stewardship website (www.copperalloystewardship.com). In taking these actions CDA does not render any judgment on whether your company or products are in violation of U.S. EPA or other federal or state regulations, but only that the statements warrant clarification to ensure a proper understanding of the claims that may be made for and appropriate uses of antimicrobial copper alloys. CDA's primary Stewardship aims are to ensure that raw material suppliers, original equipment manufacturers and consumers of products made from antimicrobial copper materials have a basic awareness and understanding of the following:

- EPA regulations that govern antimicrobial product advertising claims made in the U.S. market
- Permissible antimicrobial efficacy claims for copper-based products supported by EPA registrations
- Proper use and care of products made from antimicrobial copper materials

The following is a high-level summary of EPA regulations and registration requirements pertaining to copper-based materials and products advertised with antimicrobial effectiveness claims in the U.S. market:

- All copper-based products sold in the U.S. that claim antimicrobial effectiveness are regulated by EPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). Additional information on the EPA website is available at <http://www.epa.gov/pesticide-registration/antimicrobial-pesticide-registration>.
- Manufacturers are only permitted to advertise copper alloy-based products with antimicrobial effectiveness claims in the U.S. if the products are manufactured from EPA-registered copper alloys (e.g. brass, bronze) sourced through an EPA-registered supplier.
 - A list of registered copper alloys identified by Unified Numbering System (UNS) designations is available at https://www.copperalloystewardship.com/sites/default/files/upload//media-library/files/pdfs/us/master_epa_registered_cu_alloy_list_2018.pdf
 - A list of known EPA-registered copper alloys suppliers is available at <https://www.copperalloystewardship.com/node/14698>
 - More information on EPA requirements for antimicrobial product manufacturers is available at <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>



- Suppliers of copper alloy raw materials (e.g. sheet, tube, foil, etc.) must secure their own independent federal and state EPA registrations and comply with mandatory reporting and labeling requirements.
 - Referencing the generic EPA registrations for copper alloys secured by CDA in 2008 (EPA Reg. Nos. 82012-1 through 82012-6) does not satisfy the requirement for suppliers to obtain their own independent EPA company registrations before antimicrobial advertising claims can be made for their materials and the products made from those materials by downstream supply chain partners.
- Antimicrobial copper alloys are only registered to make public health claims against the following six bacteria: Methicillin-resistant *Staphylococcus aureus* (MRSA), Vancomycin-resistant *Enterococcus faecalis* (VRE) *Enterobacter aerogenes*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Escherichia coli* O157:H7. No claim of antimicrobial effectiveness can be made, either express or implied, with regard to organisms (including viruses, fungi and bacteria in general) other than those identified above.
- While products made from EPA-registered antimicrobial copper alloy materials have been shown to reduce microbial contamination, they do not necessarily prevent cross-contamination or infection. Claims cannot be made regarding protection from the acquisition or transmission of infectious pathogens, infections or related illnesses.
- All product marketing materials must contain EPA-mandated supplemental language about the need to clean surfaces regularly and the need to sustain standard infection control practices (see below).
- Referencing independent, peer-reviewed studies about copper alloys in marketing materials is considered an implied product claim and is not permitted. This includes making references to a variety of high quality studies that have been published in peer-reviewed journals and elsewhere discussing the antimicrobial effectiveness of copper alloys in laboratory and clinical settings. Regardless of the quality of these studies, because they have not yet been reviewed or approved by EPA they may not be mentioned in the marketing of copper alloy products.

Copper alloy product manufacturers, distributors and the facilities that utilize them for antimicrobial benefits must adhere to U.S. EPA guidelines to protect public health and safety. These guidelines include the following principles which U.S. EPA requires marketers of antimicrobial copper products to convey clearly to the customer or potential customer:

- Antimicrobial copper alloys are a supplement to and not a substitute for standard infection control practices.
- Users must continue to follow all current infection control and cleaning practices.
- Routine cleaning to remove dirt and grime is necessary for good sanitation and to assure the effective performance of the antimicrobial copper alloy surface.
- Antimicrobial copper alloys must not be coated in any way (i.e. with waxes, paints, lacquers, etc.) in order to be effective. The natural tarnishing of copper alloys does not compromise their antimicrobial property.

In conclusion, CDA strongly recommends that you carefully review all product claims made on websites and in other marketing materials to ensure compliance with the federal and state EPA regulations summarized above which are applicable to all copper-based products advertised with antimicrobial effectiveness claims in the U.S. market.

CDA is a not-for-profit organization that provides market development, engineering and information services for the U.S. copper industry. CDA does not produce, sell, or distribute any product. The companies who produce various forms of copper (e.g. sheet, strip, plate) make and sell antimicrobial copper alloy raw materials and products. It is not our intent to limit the ability of companies to market copper products with antimicrobial claims. Our intent is to comply with our obligations related to the EPA registrations that govern such products. Please visit our Stewardship website at www.copperalloystewardship.com for more in-depth information on antimicrobial copper alloys and their proper use and care.

Respectfully,



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