Proposed Registration Document PRD2013-23

Metallic Copper

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Overview

Proposed Registration Decision for Metallic Copper

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Copper TGAI and Antimicrobial Copper Alloys Group I, II, III, IV, V and VI, containing the technical grade active ingredient metallic copper, to be used to manufacture products with inherent antimicrobial properties.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Copper TGAI and Antimicrobial Copper Alloys Group I, II, III, IV, V and VI.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on metallic copper, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on metallic copper, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Metallic Copper?

Metallic Copper, in the form of six different alloys, may be used to manufacture products with inherent antimicrobial properties. Although the mode of action has not been confirmed, scientific literature suggests that the toxicity of surfaces made of solid copper involves the release of copper ionic species toxic to the cell membrane, and the generation of superoxide resulting in arrested respiration and DNA breakdown as the first stages of cell death.

Health Considerations

Can Approved Uses of Metallic Copper Affect Human Health?

Metallic Copper is unlikely to affect human health when it is used according to label directions.

Potential exposure to metallic copper may occur when handling, installing, and touching products fabricated with the end-use products, Antimicrobial Copper Alloys Group I, Antimicrobial Copper Alloys Group II, Antimicrobial Copper Alloys Group III, Antimicrobial Copper Alloys Group IV, Antimicrobial Copper Alloys Group V, and Antimicrobial Copper Alloys Group VI (hereafter referred to as Antimicrobial Copper Alloys Group I to VI). When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, metallic copper, was of low acute toxicity via the dermal route of exposure. Metallic copper was non-irritating to the skin and eyes, but instances of acute contact dermatitis (ACD)[5] in sensitive individuals have been reported in the open literature.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

5 According to the Canadian Centre for Occupational Health and Safety (CCOHS), the current number of ACD cases in Canada is unknown but contact dermatitis, marked by red, itchy inflammation of the skin, is reversible and is not life-threatening

The acute toxicity of the end-use products, Antimicrobial Copper Alloys Group I to VI, were low via the dermal route of exposure. They were non-irritating to the skin and eyes, but cause allergic skin reaction; consequently, the hazard signal words “Potential skin sensitizer” are required on the label.

Metallic copper did not cause effects in developing young and did not damage genetic material.

The risk assessment protects against the effects of metallic copper by ensuring that the level of human exposure is well below the lowest dose at which effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

The proposed uses of Antimicrobial Copper Alloys Group I to VI are not food or feed related. Dietary risks from food and drinking water are negligible.

Occupational Exposure

Occupational risks are not of concern when Antimicrobial Copper Alloys Group I to VI are used according to the proposed label directions, which include protective measures.

A risk assessment conducted for individuals handling and installing products fabricated with Antimicrobial Copper Alloys Group I to VI indicated that risk for adults is not of concern when the products are used according to label directions.

Environmental Considerations

An environmental assessment was not required for this application based on the proposed use pattern.

Value Considerations

What Is the Value of Antimicrobial Copper Alloys Group I to VI?
The articles manufactured with the Antimicrobial Copper Alloys Group I to VI will have a surface providing continuous sanitizing action.

Because the antimicrobial activity comes from the metal itself, the action is continuous and cannot be removed or wiped off from the surface, while spray sanitizers have to be re-applied often, especially if the treated surfaces are touched or contaminated frequently during a day. These alloys will also provide a supplemental antimicrobial action between routine cleanings. Since the copper alloys are solids, no chemicals will leach from their surface upon contact.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

No further risk-reduction measures are required.

Next Steps

Before making a final registration decision on metallic copper, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on metallic copper (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Metallic Copper

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Copper
Function	Antimicrobial
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Copper
2. Chemical Abstracts Service (CAS)	Copper
CAS number	7440-50-8
Molecular formula	Cu
Molecular weight	63.546
Structural formula	Cu
Purity of the active ingredient	99.98

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product—Copper Technical

Property	Result
Colour and physical state	Reddish solid
Odour	Waived
Melting range	1083.4°C
Boiling point or range	N/A as product is a solid
Density	8.94 g/mL
Vapour pressure at 20°C	Negligible
Ultraviolet (UV)-visible spectrum	As copper metal reflects red, it absorbs the remaining wavelengths of visible light (from ~300 to 600 nm).
Solubility in water	Not soluble
Solubility in organic solvents	Not soluble

n-Octanol-water partition coefficient (K_{ow})	Not soluble in either water or octanol
Dissociation constant (pK_a)	Does not dissociate
Stability (temperature, metal)	Stable in air under normal conditions. It will slowly react with air to form a layer of cuprous oxide, Cu_2O.

End-Use Product—Antimicrobial Copper Alloys Groups I to VI

Property	Group I	Group II	Group III	Group IV	Group V	Group VI
Colour	Varies depending on the alloy					
Odour	Waived					
Physical state	Solid					
Formulation type	Solid					
Guarantee	96.2%	91.3%	82.6%	73.0%	66.5%	62.0%
Container material and description	Packaging is optional and can vary based on marketplace requirements					
Density	7.2–9.4 g/cm^3					
pH of 1% dispersion in water	Waived					
Oxidizing or reducing action	Each alloy is a reductant and can be oxidized by strong mineral acids; also can be slowly oxidized by air. Stable in contact with reducing agents.					
Storage stability	Waived as copper alloys are known to be stable for decades					
Corrosion characteristics	Waived as alloys are relatively inert and in this case are machined into fixtures that are to be used without packaging					
Explodability	Not explosive					

1.3 Directions for Use

The copper alloys will be used in the manufacture and fabrication of non-food contact touch surfaces components. These components will be used in the following areas:

- Healthcare facilities
- Community facilities (public and commercial buildings)
- Common areas in multi-residence dwellings (for example, apartment/condo buildings)
- Mass transit facilities
- Kitchen and bathrooms in homes and apartments

1.4 Mode of Action

Although the mode of action has not been confirmed, scientific literature suggests that when used in a solid surface, copper toxicity to bacteria could start with the oxidation of the fatty acids in the cell membrane. The copper could also break down DNA and interfere with bacterial respiration. A bacterial reduction of 99.9% within 2 hours is expected from these surfaces. Following repeated challenges, the continuous sanitizing action is also expected to provide 99% reduction of bacteria.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and impurities in the technical product have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulations has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

Not applicable for environmental media, as environmental assessment is not required for these types of products.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for metallic copper was conducted. The database is complete, consisting of peer reviewed published journal articles and foreign reviews currently required for hazard assessment purposes. The scientific quality of the data is acceptable and the database is considered adequate to define the majority of toxic effects that may result from exposure to metallic copper.

The applicant was not required to submit additional toxicology information for the TGAI, Copper TGAI or for any of the end-use products (EPs), Antimicrobial Copper Alloys Group I to VI.

Although the physical form of metallic copper as a sheet is not practical for testing the acute oral or inhalation toxicity, the toxicity of copper has been well characterized. Copper TGAI is expected to be of low acute dermal toxicity and is not expected to be irritating to the skin or eyes, but there have been recorded instances of dermal sensitization in humans exposed to copper coins, copper ornaments and copper jewelry. The antimicrobial copper alloy EPs will be in a physical form that will not permit direct ingestion or inhalation. All of the antimicrobial copper alloys are expected to be of low acute toxicity via the dermal route of exposure. The copper alloys are not expected to be skin or eye irritants, but at least one formulant is a known skin sensitizer.

Based on a long history of use of metallic copper in fabricated products, it is not expected that exposure to metallic copper will result in short-term toxicity, developmental toxicity, or genotoxicity.

Results of the toxicology studies conducted on laboratory animals with Antimicrobial Copper Alloys Group I to VI are summarized in Appendix I, Tables 1 and 2.

Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website. Incidents from Canada and the United States were searched and reviewed for copper metal. As of October 4, 2013, there were no health-related incident reports submitted to the PMRA or the United States for end-use products containing metallic copper.

3.2 Occupational and Bystander Risk Assessment

3.2.1 Toxicological Endpoints

Occupational exposure to Antimicrobial Copper Alloys Group I to VI is characterized as short-term intermittent and is predominantly by the dermal route.

3.2.1.1 Dermal Absorption

Dermal contact with Antimicrobial Copper Alloys Group I to VI is not expected to result in absorption of metal ions.

3.2.2 Occupational Exposure and Risk

Handling and installing the fabricated copper alloy products will involve dermal exposure, the degree of which will depend on the nature of a given task and the duration of each individual task. It is expected that repeated contact with products fabricated with the copper alloys may result in exposure to sufficient residual metal ions, to trigger ACD in individuals with metal sensitivities.

3.2.2.1 Mixer/loader/applicator Exposure and Risk Assessment

There is potential for exposure to workers applying products fabricated with Antimicrobial Copper Alloys Group I to VI. Dermal exposure estimates for workers installing the fabricated products could not be quantified, but is expected to be short-term in duration and to occur primarily by the dermal route.

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted.

3.2.2.2 Postapplication Worker Exposure and Risk

There is potential for exposure to workers re-entering areas treated with products fabricated from Antimicrobial Copper Alloys Group I to VI during clean-up and adjustment activities. Given the nature of the activities performed, dermal contact with treated surfaces should be short-term in duration.

3.2.3 Residential Exposure and Risk Assessment

Since the fabricated copper alloy products will not be labelled after being installed, a risk assessment of residential exposure to the fabricated copper alloy products was not possible, but it is expected that individuals will be subject to repeated short-term dermal exposure.

4.0 Impact on the Environment

An environmental assessment was not required for this application based on the proposed use pattern.

5.0 Value

5.1 Effectiveness Against Pests

Several laboratory trials were provided for each alloy in support of efficacy against bacteria. Data have shown the ability of copper alloys to achieve 99.9% reduction of a single inoculation of bacteria following a 2-hour contact time and reduction of bacterial populations by up to 99% after repeated challenges. The efficacy of the copper surfaces was not diminished following physical contact and abrasion. In addition, the mode of action, pest problem and the efficacy against viruses, fungi and yeasts were supported by published papers and scientific rationales. Finally, a published paper reporting a full-scale trial carried out in hospitals was provided. When coated with copper, the objects close to the patients had their overall bacterial population significantly reduced when compared to stainless steel controls.

5.1.1 Acceptable Efficacy Claims

Laboratory testing has shown that when cleaned regularly this surface:

- Kills greater than 99.9% of Gram-negative and Gram-positive bacteria within 2 hours of exposure.
- Delivers continuous and ongoing antibacterial action (continues to kill 99% of bacteria even after repeated contaminations).

5.2 Consideration of Benefits

The availability of various objects manufactured or coated with copper may provide additional tools to reduce microbial contamination between routine cleaning or sanitation steps, especially when objects are frequently touched by several persons or by sensitive individuals.

5.3 Economics

No market analysis was done for this application.

5.4 Sustainability

5.4.1 Survey of Alternatives

No other products are currently available with the characteristics of being a material with continuous and built-in sanitizing capacity.

5.4.2 Information on the Occurrence or Possible Occurrence of the Development of Resistance

No information has been provided by the applicant. However, scientific literature suggests that while the presence of high concentrations of cupric ions in the environment can promote the selection of copper resistant microorganisms, the hard surface made of copper alloys is not expected to trigger resistance due to the contact killing mode of action.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

Metallic copper and the six associated EPs, were assessed in accordance with the PMRA Regulatory Directive DIR99-03.[6]

- Copper alloys, as used in the manufacture of touch surfaces, do not meet the Track 1 criteria and will not form any transformation products which meet the Track 1 criteria.

- There are also no formulants, contaminants or impurities present in the EPs that would meet the TSMP Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the EP are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[7] The list is used as described in the PMRA Notice of Intent NOI2005-01[8] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[9] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Copper TGAI, Antimicrobial Copper Alloys Group I, Antimicrobial Copper Alloys Group II, Antimicrobial Copper Alloys Group III, Antimicrobial Copper Alloys Group IV, Antimicrobial Copper Alloys Group V, and Antimicrobial Copper Alloys Group VI do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

The use of formulants in registered pest control products is assessed on an on-going basis through PMRA formulant initiatives and DIR2006-02.

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6 Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

7 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-11-30) pages 2641-2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613: *Part I Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

8 Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*

9 Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for metallic copper is adequate to define the majority of toxic effects that may result from exposure to metallic copper. In sheet form, metallic copper's acute toxicity via the oral and inhalation route could not be determined, but is expected to be of low acute toxicity via the dermal route of exposure. It is not a skin or eye irritant, but there have been reports of ACD in the public literature. Metallic copper is of low short-term toxicity, is not associated with prenatal developmental toxicity, and is not genotoxic. Antimicrobial Copper Alloys Group I to VI are expected to have very similar toxicological profiles to metallic copper with the exception that they contain at least one skin sensitizer in each EP and must be labelled accordingly.

The Antimicrobial Copper Alloys Group I to VI are to be used as required, thus it is necessary to ensure that incidental dermal exposure to individuals manufacturing and installing the fabricated products is minimized.

Exposure to individuals handling Antimicrobial Copper Alloys Group I to VI during manufacture or installation of the fabricated products is not expected to result in unacceptable risk when the end-use products are used according to label directions.

7.2 Environmental Risk

An environmental assessment was not required for this application based on the proposed use pattern.

7.3 Value

The information submitted in support of the copper alloys was adequate to demonstrate its value for use against bacteria, viruses, fungi and yeasts. The six solid copper alloys proposed will be used to manufacture objects or coat fabricated products with antimicrobial properties. These products could be used in the following areas:

- Healthcare facilities
- Community facilities (public and commercial buildings)
- Common areas in multi-residence dwellings (for example, apartment/condo buildings)
- Mass transit facilities
- Kitchen and bathrooms in homes and apartments

The copper alloys will help in reducing the proliferation of microorganisms on surfaces that are frequently touched. However, it is also understood that the use of the copper surfaces will not replace routine cleaning and will not be used as a substitute for standard infection control practices in healthcare facilities where it will be used.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Copper TGAI and Antimicrobial Copper Alloys Group I, II, III, IV, V and VI, containing the technical grade active ingredient metallic copper, to be used to manufacture products with inherent antimicrobial properties.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

ACD	acute contact dermatitis
CAS	Chemical Abstracts Service
CCOHS	Canadian Centre for Occupational Health and Safety
cm	centimetres
DNA	deoxyribonucleic acid
EP	end-use product
g	gram
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	*n*–octanol-water partition coefficient
mL	millilitre
N/A	not applicable
nm	nanometre
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Toxicity Profile of Antimicrobial Copper Alloys Group I to VI Containing Copper Metal

Study Type/PMRA #	Study Results
Acute dermal toxicity PMRA # 2336988, 2337009	Based on a long history of use and available information, metallic copper is expected to be of low acute toxicity.
Primary eye irritation PMRA # 2336988, 2337009	Based on a long history of use and available information, metallic copper is not expected to be an eye irritant.
Primary skin irritation PMRA # 2336988, 2337009	Based on a long history of use and available information, metallic copper is not expected to be a skin irritant.
Dermal sensitization PMRA # 2336988, 2337003, 2337009, 2338410, 2338411, 2338417, 2338424, 2338430, 2338441, 2338444, 2338446, 2338450	Based on available information, there have been instances of ACD reported in the medical literature for metallic copper.

Table 2 Toxicity Profile of Technical Copper Metal

Study Type/PMRA #	Study Results
Acute dermal toxicity PMRA # 2336988, 2337009, 2338436	Based on a long history of use and available information, metallic copper is expected to be of low acute toxicity.
Primary eye irritation PMRA # 2336988, 2337009	Based on a long history of use and available information, metallic copper is not expected to be an eye irritant.

Study Type/PMRA #	Study Results
Primary skin irritation PMRA # 2336988, 2337009	Based on a long history of use and available information, metallic copper is not expected to be a skin irritant.
Dermal sensitization PMRA # 2336988, 2337003, 2337009, 2338410, 2338411, 2338417, 2338424, 2338430	Based on available information, there have been instances of ACD reported in the medical literature for metallic copper.
Short-term toxicity PMRA # 2336988, 2337009	Based on a long history of use and available information, exposure to metallic copper is not expected to result in short-term toxicity.
Prenatal developmental toxicity PMRA # 2336988, 2337009	Based on a long history of use and available information, exposure to metallic copper is not expected to result in developmental toxicity.
Genotoxicity: bacterial reverse mutation assay PMRA # 2336988, 2337009	Based on a long history of use and available information, metallic copper is not expected to be mutagenic.
Genotoxicity: *in vitro* mammalian cell assay PMRA # 2336988, 2337009	Based on a long history of use and available information, metallic copper is not expected to be genotoxic.

Table 3 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Proposed label claim	Supported claim
Manufacture and fabrication of touch surface components for use in: o Healthcare facilities o Community facilities (including various public and commercial buildings) o Residential buildings (including homes, apartments, apartments buildings and other residences) o Mass transit facilities o Other	Manufacture and fabrication of non-food contact touch surfaces components for use in: o Healthcare facilities o Community facilities (public and commercial buildings) o Common areas in multi-residence dwellings (for example, apartment/condo buildings) o Mass transit facilities o Kitchen and bathrooms in homes and apartments
Laboratory testing has shown that when cleaned regularly this surface: 1.-Continuously reduces bacteria* contamination, achieving 99.9% reduction within 2 hours of exposure. 2.-Kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within 2 hours of exposure. 3.-Delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours. 4.-Kills greater than 99.9% of bacteria* within two hours and continues to kill 99% of bacteria* even after repeated contaminations. 5.-Helps inhibit the buildup and growth of bacteria* within 2 hours of exposure between routine cleaning and sanitizing steps. 6.-[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).	Laboratory testing has shown that when cleaned regularly this surface: 1.-Reduces bacteria contamination, achieving 99.9% reduction within 2 hours of exposure. 2.-Kills greater than 99.9% of Gram-negative and Gram-positive bacteria within 2 hours of exposure. 3.-Delivers continuous and ongoing antibacterial action. - Remains effective in killing greater than 99.9% of bacteria within 2 hours. 4.-Kills greater than 99.9% of bacteria within two hours and continues to kill 99% of bacteria even after repeated contaminations. 5.-Helps inhibit the buildup and growth of bacteria within 2 hours of exposure between routine cleaning and sanitizing steps. 6.-[This product/component name] is made (out of)(from) a (copper)(touch) surface that continuously kills 99% of bacteria left behind [by dirty hands][on the surface] - [This product/component name] is made (out of)(from) a (copper)(touch) surface that kills more than 99.9% of bacteria within 2 hours.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2155844	2012, DACO Compilation for Copper, DACO: 2.1,2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.13.1,2.13.2,2.13.3,2.13.4,2.14.1,2.14.2,2.14.4,2.14.6,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI
2229735	2004, ASTM B115-00, DACO: 2.13.3
2229736	2012, Sources of Copper, DACO: 2.13.3
2156480	Product Identification, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
2156481	2006, Antimicrobial Alloy Group I - Product Properties - Group A, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.2 CBI
2156482	2011, Antimicrobial Copper Alloys Group I Product Properties - Group A - Supplemental, DACO: 3.3.1 CBI
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2.0 Human and Animal Health

None.

3.0 Environment

None.

4.0 Value

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B. Additional Information Considered

i) Published Information

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3.0 Environment

None.

4.0 Value

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