UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 16, 2015

MEMORANDUM

Subject: Efficacy Review for EPA File Symbol 88450-E, LuminOre Copper Touch Antimicrobial Copper Alloy Surfaces; DP Barcode: 426173

From: Marcus Rindal, Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

To: John Hebert PM 33/Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: LuminOre, Incorporated
6060 Corte del Cedro
Carlsbad, CA 92011

Formulation from the Label:

Active Ingredient(s)	% by wt.
Copper*	62.5%
Other Ingredients	37.5%
Total	100.0%

* Contains 2.8 oz. of copper per ft^2

I BACKGROUND

The product, LuminOre Copper Touch Antimicrobial Copper Alloy Surfaces (EPA File Symbol 88450-E) is seeking a new registration to support the following sanitization claims:

- Hard surface as a sanitizer
- Continuous Bacterial Hard Surfaces as a Sanitizer
- Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces

Testing was conducted against 5 test organisms and each of the three sanitizer test methods. LuminOre Copper Touch Antimicrobial Copper Alloy Surfaces is a copper coated substrate that provides continuous antimicrobial activity. The surface is a thin layer of copper which is bound to the substrate. The substrates proposed for use in the product are metal, plastic, and wood/wood composites. Several discussions were held between the registrant (LuminOre Inc.) and the Agency prior to the conduct of the efficacy studies. It was agree that an aluminum-magnesium substrate should be used for all efficacy tests. In addition, the protocols used for LuminOre Copper Touch Antimicrobial Copper Alloy Surfaces efficacy studies are the same protocols that were used for the efficacy studies performed with the copper alloys (Reg. No. 82021-2). Efficacy data were generated at MicroBioTest located at 105 Carpenter Drive in Sterling, VA, 20164.

The current data package contained a letter from the registrant's representative, Lewis & Harrison (dated February 11, 2015), EPA Form 8670-4 (Confidential Statement of Formula), Statement of No Data Confidentiality for each study, Good Laboratory Practices (GLP) Compliance Statement for each study, efficacy studies (MRID Nos. 495658-05 through 495658-12), and the proposed label.

II USE DIRECTIONS

The product is proposed to support claims for supplemental sanitizer with additional claims for continuous and…The product will be molded and cut for use in tables, desks, non-food contact counters, over the bed tables, bed side tables, hand rails, carts, doors, door push plates, towel bars, floor tiles, ceiling tiles, instrument casings and molded knobs, shopping carts, trays, soap holders, and light switches/plates. Directions on the proposed label provided the following instructions for the preparation, use, and maintenance of the product:

> Clean and sanitize according to standard practice. Health care facilities must maintain the product in accordance with infection control guidelines. The use of this 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. This surface has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.
>
> This surface may be subject to recontamination and the level of active bacteria at any time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order to have proper antimicrobial effect, this product must be cleaned and maintained according to the directions for use.

Do not wax, paint, lacquer, varnish, or otherwise coat this product.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of this surface. Cleaning agents typically used for traditional hard, non-porous touch surfaces are permissible. The appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. Normal tarnishing or wear of this surface will not impair antibacterial effectiveness.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Copper Alloy Surfaces as a Sanitizer: The effectiveness of copper alloy surfaces as sanitizers must be supported by data that show that the product (i.e., surface) will substantially reduce the numbers of test bacteria. Tests must be performed against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Results must show a bacterial reduction of at least 99.9 percent over the carrier quantitation control. The carrier quantitation control must yield a minimum geometric mean of 2.0×10^4 CFU/carrier. Claims for additional bacteria will be considered only if acceptable sanitizer efficacy is demonstrated for *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Products that are represented as residual self-sanitizers and/or continuous reduction sanitizers must demonstrate acceptable sanitizer efficacy before additional claims are considered. Agency standards and required label language are presented in EPA's "Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer." To support a supplemental sanitization claim on a copper alloy surface, a 99.9% reduction in numbers of the test organism(s) must be obtained as compared to the carrier quantitation control. Efficacy data can support the claim "kills greater than 99.9% of bacteria* within two hours (* Includes list of tested organisms). Claims are limited to indoor, hard, non-porous surfaces where cleaning practices are consistent. The following language is required on the registered products, the use of a copper surface is a supplement to and not a substitute for standard infection control practices; user must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. The copper surface material has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.

Residual Self-Sanitizing Activity of Copper Alloy Surfaces: The effectiveness of copper alloy surfaces to provide residual self-sanitizing activity must be supported by data that show that the product (i.e., surface) will substantially reduce the number of test bacteria. An initial sanitizer evaluation, a simulated wear-and-re-inoculation evaluation, and a final sanitizer evaluation must be performed. Tests must be performed against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Results must show a reduction of the total number of organisms by at least 99.9 percent on the surface within/for the prescribed exposure time. The control plates must show a minimum of 2×10^4 CFU/carrier for the test to be considered valid. Claims for additional bacteria will be considered only if acceptable sanitizer efficacy is demonstrated for *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Products that are represented as residual self-sanitizers and/or continuous reduction sanitizers must demonstrate acceptable sanitizer efficacy before additional claims are considered. Agency standards and required label language are presented in EPA's "Test Method for Residual Self-Sanitizing Activity of Copper Alloy Surfaces." To be defined as a residual

self-sanitizer, the test material must reduce the total number of organisms by at least 99.9% on the surface within the prescribed exposure time.
Claims are limited to indoor, hard, non-porous surfaces where cleaning practices are consistent. The acceptable claim indicates the surface kills greater than 99.9% of bacteria* for 24 hours.
*Includes list of tested organisms.

Copper Alloy Surfaces as a Continuous Reduction Sanitizer: The effectiveness of copper alloy surfaces to provide continuous reduction of bacterial contamination must be supported by data that show that the product (i.e., surface) will substantially reduce the number of test bacteria. Tests must be performed against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Results must show a bacterial reduction of at least 90 percent over the carrier quantitation control at all recovery times over the 24-hour inoculation and exposure period. The carrier quantitation control must yield a minimum geometric mean of 2.0×10^4 CFU/carrier. Claims for additional bacteria will be considered only if acceptable sanitizer efficacy is demonstrated for *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Products that are represented as residual self-sanitizers and/or continuous reduction sanitizers must demonstrate acceptable sanitizer efficacy before additional claims are considered. Agency standards and required label language are presented in EPA's "Test Method for the Continuous Reduction of Bacterial Contamination on Copper Alloy Surfaces."

General Considerations Regarding Claims and Labeling
The following language is required on the registered products, the use of a copper surface is a supplement to and not a substitute for standard infection control practices; user must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. The copper surface material has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.

Proper Care and Use of Antimicrobial Copper Surfaces: The use of copper surfaces does not replace standard infection control procedures and good hygienic practices. Antimicrobial copper surfaces must be cleaned and sanitized according to standard practice. Heath 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.

Cleaning Directions: Routine cleaning to remove dirt and filth is necessary for good sanitization and to assure the effective antibacterial performance of the copper surfaces. 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.

This product must not be waxed, painted, lacquered, varnished, or otherwise coated.

IV SYNOPSIS OF SUBMITTED EFFICACY STUDIES

1. MRID No. 495658-07, "Efficacy Evaluation of Copper Enhanced Hard Surfaces as a Sanitizer" using LuminOre Copper/Nickel by Angela Hollingsworth. Study Completion Date – February 4, 2015. Laboratory Project Identification Number: 872-102.

The product was tested against *Staphylococcus aureus* (ATCC# 6538) and *Enterobacter aerogenes* (ATCC# 13048). Three lots (Lot Nos. 092314A, 092414A, and 092414B) of the product, LuminOre Copper/Nickel were tested using Protocol No. LUM.1a.06.16.14 (copy provided). A control sample, designated as Non Treated Coupons and assigned DS No. E532, was provided and included in the test system. The test system included 5 carrier replicates/lot and 3 control carrier replicates per test organism. Organic soil described as 0.25 mL of heat-inactivated fetal bovine serum plus 0.05 mL of Triton X-100 solution added to 4.70 mL of the bacteria suspension per 5 mL to yield at 5% FBS and 0.01% Trition X-100 soil load. An aliquot, 0.02 mL, of the inoculum was placed onto each sterile and control article carrier. The inoculum was spread to within approximately ⅛" of the edge of the carrier. The carriers were allowed to dry with lids ajar for 30 minutes under ambient conditions. The contact time began immediately after drying. At the conclusion of the 120 minute contact time, each carrier was transferred to a jar containing 20 mL of neutralizer. Each jar was sonicated for five minutes and then rotated by hand to mix. Within one hour after sonication, serial dilutions were prepared using PBS (10^{-1} and 10^{-4}). Duplicate 1.0 mL aliquots from each jar/dilution (10^{0}-10^{-4}) were plated using TSA pour plates. For *S. aureus*, plates were incubated for 48±4 hours at 35-37°C; for *E. aerogenes* plates were incubated for 48±4 hours at 25-30°C. Controls included those for carrier quantitation, purity, sterility, viability, neutralizer effectiveness control, and microorganism confirmation.

2. MRID No. 495658-08, "Efficacy Evaluation of Copper Enhanced Hard Surfaces as a Sanitizer Supplemental" using LuminOre Copper/Nickel by Angela Hollingsworth. Study Completion Date – February 4, 2015. Laboratory Project Identification Number: 872-104.

The product was tested against *Pseudomonas aeruginosa* (ATCC# 15442), Methicillin Resistant *Staphylococcus aureus* (ATCC# 33592) and *Escherichia coli* O157:H7 (ATCC# 35150). Two lots (Lot Nos. 092314A and 092414A) of the product, LuminOre Copper/Nickel were tested using Protocol No. LUM.4a.06.16.14 (copy provided). A control sample, designated as Non Treated Coupons and assigned DS No. E532, was provided and included in the test system. The test system included 5 carrier replicates/lot and 3 control carrier replicates per test organism. Organic soil described as 0.25 mL of heat-inactivated fetal bovine serum plus 0.05 mL of Triton X-100 solution added to 4.70 mL of the bacteria suspension per 5 mL to yield at 5% FBS and 0.01% Trition X-100 soil load. An aliquot, 0.02 mL, of the inoculum was placed onto each sterile and control article carrier. The inoculum was spread to within approximately ⅛" of the edge of the carrier. The carriers were allowed to dry with lids ajar for 30 minutes under ambient conditions. The contact time began immediately after drying. At the conclusion of the 120 minute contact time, each carrier was transferred to a jar containing 20 mL of neutralizer. Each jar was sonicated for five minutes and then rotated by hand to mix. Within one hour after sonication, serial dilutions were prepared using PBS (10^{-1} and 10^{-4}). Duplicate 1.0 mL aliquots from each jar/dilution (10^{0}-10^{-4}) were plated using TSA pour plates. For all three test organisms, plates were incubated for 48±4 hours at 35-37°C. Controls included

those for carrier quantitation, purity, sterility, viability, neutralizer effectiveness control, and microorganism confirmation.

3. **MRID No. 495658-09, "Efficacy Evaluation of Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as a Sanitizer," using LuminOre Copper/Nickel by Angela Hollingsworth. Study Completion Date – February 4, 2015. Laboratory Project Identification Number: 872-106**.

The product was tested against *Staphylococcus aureus* (ATCC# 6538) and *Enterobacter aerogenes* (ATCC# 13048). Three lots (Lot Nos. 092314A, 092414A, and 092414B) of the product, LuminOre Copper/Nickel were tested using Protocol No. LUM.2b.06.16.14 (copy provided). A control sample, designated as Non Treated Coupons and assigned DS No. E532, was provided and included in the test system. The test system included 5 carrier replicates/lot and 3 control carrier replicates per test organism. Organic soil described as 0.25 mL of heat-inactivated fetal bovine serum plus 0.05 mL of Triton X-100 solution added to 4.70 mL of the bacteria suspension per 5 mL to yield at 5% FBS and 0.01% Trition X-100 soil load. All test and control surfaces were inoculated at staggered intervals with 5 µL of the test organism. The inoculum was spread to within approximately ⅛" of the edge of the carrier. The contact time initiated immediately after inoculation. This initial inoculation was considered as "time zero". Carriers were re-inoculated in the same manner at 3, 6, 9, 12, 15, 18, and 21 hours. The carriers were dried at ambient conditions for the duration of exposure. The exposure period began with the initial "time-zero" inoculation. The sets not removed for quantitative recovery were inoculated in the same manner at 3, 6, 9, 12, 15, 18, and 21 hours post "time-zero" inoculation. The sets for quantitative recovery were removed at 2 (single inoculation), 6 (two inoculations), 12 (four inoculations), 18 (six inoculations), and 24 (8 inoculations) hours. At the conclusion of the applicable contact times for each set of surfaces, each carrier was transferred to a jar containing 20 mL of neutralizer at the appropriate staggered intervals. Each jar was sonicated for five minutes and then rotated by hand to mix. Within one hour after sonication, serial dilutions were prepared using PBS (10^{-1} – 10^{-4}). Duplicate 1.0 mL aliquots from each jar/dilution (10^{0} – 10^{-4}) were plated using TSA pour plates. For *S. aureus*, plates were incubated for 48±4 hours at 35-37°C; for *E. aerogenes* plates were incubated for 48±4 hours at 25-30°C. Controls included those for carrier quantitation, purity, sterility, viability, neutralizer effectiveness control, and microorganism confirmation.

4. **MRID No. 495658-10, "Efficacy Evaluation of Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as a Sanitizer Supplemental," using LuminOre Copper/Nickel by Angela Hollingsworth. Study Completion Date – February 4, 2015. Laboratory Project Identification Number: 872-110**.

The product was tested against *Pseudomonas aeruginosa* (ATCC# 15442), Methicillin Resistant *Staphylococcus aureus* (ATCC# 33592) and *Escherichia coli* O157:H7 (ATCC# 35150). Two lots (Lot Nos. 092314A and 092414A) of the product, LuminOre Copper/Nickel were tested using Protocol No. LUM.5a.06.16.14 (copy provided). A control sample, designated as Non Treated Coupons and assigned DS No. E532, was provided and included in the test system. The test system included 5 carrier replicates/lot and 3 control carrier replicates per test organism. Organic soil described as 0.25 mL of heat-inactivated fetal bovine serum plus 0.05 mL of Triton X-100 solution added to 4.70 mL of the bacteria suspension per 5 mL to yield at 5% FBS and 0.01% Trition X-100 soil load. All test and control surfaces were inoculated at staggered intervals with 5

µL of the test organism. The inoculum was spread to within approximately ⅛" of the edge of the carrier. The contact time initiated immediately after inoculation. This initial inoculation was considered as "time zero". Carriers were re-inoculated in the same manner at 3, 6, 9, 12, 15, 18, and 21 hours. The carriers were dried at ambient conditions for the duration of exposure. The exposure period began with the initial "time-zero" inoculation. The sets not removed for quantitative recovery were inoculated in the same manner at 3, 6, 9, 12, 15, 18, and 21 hours post "time-zero" inoculation. The sets for quantitative recovery were removed at 2 (single inoculation), 6 (two inoculations), 12 (four inoculations), 18 (six inoculations), and 24 (8 inoculations) hours. At the conclusion of the applicable contact times for each set of surfaces, each carrier was transferred to a jar containing 20 mL of neutralizer at the appropriate staggered intervals. Each jar was sonicated for five minutes and then rotated by hand to mix. Within one hour after sonication, serial dilutions were prepared using PBS (10^{-1} – 10^{-4}). Duplicate 1.0 mL aliquots from each jar/dilution (10^{0} – 10^{-4}) were plated using TSA pour plates. Plates were incubated for 48±4 hours at 35-37°C. Controls included those for carrier quantitation, purity, sterility, viability, neutralizer effectiveness control, and microorganism confirmation.

5. **MRID No. 495658-11, "Efficacy Evaluation of Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces," using LuminOre Copper/Nickel by Angela Hollingsworth. Study Completion Date: February 4, 2015. Laboratory Project Identification Number: 872-108.**

The product was tested against *Staphylococcus aureus* (ATCC# 6538) and *Enterobacter aerogenes* (ATCC# 13048). Three lots (Lot Nos. 092314A, 092414A, and 092414B) of the product, LuminOre Copper/Nickel were tested using Protocol No. LUM.3a.06.16.14 (copy provided). A control sample, designated as Non Treated Coupons and assigned DS No. E532, was provided and included in the test system. The test system included 4 carrier replicates/lot and 8 control carrier replicates per test organism (4 initial carriers and 4 final carriers). Organic soil described as 0.25 mL of heat-inactivated fetal bovine serum plus 0.05 mL of Triton X-100 solution added to 4.70 mL of the bacteria suspension per 5 mL to yield at 5% FBS and 0.01% Trition X-100 challenge.

Initial Sanitizer Test. Each lot of the test surface carrier and control was inoculated with 10 µL of the prepared initial sanitizer inoculum. Carriers were allowed to dry for 30-40 minutes at 35-37°C at 38-42% relative humidity. Immediately after drying, the 120 minute contact time was initiated. At the conclusion of the contact time, each carrier was transferred to a jar containing 30 mL of neutralizer at the appropriate staggered intervals. Each jar was subsequently sonicated for 20±2 seconds. The samples were then mixed on an orbital shaker for 3-4 minutes at 250 rpm. Serial dilution were then prepared using sterile deionized water. Duplicate 1.0 mL aliquots from each jar/dilution (10^{0} – 10^{-2}) for the test carriers and (10^{2} – 10^{-4}) for the control carriers were plated using TSA pour plates. *S. aureus* plates were incubated for 48±4 hours at 35-37°C. *E. aerogenes* plates were incubated for 48±4 hours at 25-30°C.

Simulated Wear and Reinoculation. Prior to inoculation, the abrasion tester was set to a speed of 2.25 –2.50 for total surface contact time of approximately 4-5 seconds for one complete cycle. The speed was measured with a stopwatch, and the machine's cycle was calibrated by adjusting the number counter to 1, 5, 10, and 20 and verifying cycle time. It will be set so that one pass on the abrasion tester with the surfaces is equal to a contact time of approximately 2 seconds. A wear cycle was identified as one pass to the left and a return pass to the right on the Gardner scrubber with an abrasion boat fitted with a foam

liner and dry cotton cloth. The weight of the fully assembled weight boat was determined to be 1084 ± 1g prior to use. For each lot of the test surface, per microorganism, four carriers will be inoculated at staggered intervals with 0.01 mL of the prepared simulated wears inoculum using a calibrated pipette. The inoculum will be spread to within approximately 1/8th inch of the edge of the carrier and the carriers will be allowed to dry for 30-40 minutes at 35-37°C. These inoculation and drying procedures will be designated as "reinoculated and drying." To initiate the wear cycles, each carrier was subjected to a dry wear cycle using the Gardco Washability and Wear Tester and the fully assembled wieght boat. Fifteen (15) minutes after the initial wear cycle, each carrier was re-inoculated and dried at ambient temperature. Each carrier was then subjected to a wet wear cycle using the Gardco Washability and Wear Tester and the fully assembled wieght boat. The fully assembled weight boat was sprayed for one second with sterile deionized water using a Preval sprayer from a distance of 75±1 cm for not more than one second. At least 15 minutes after the secondary wear cycle, each carrier was re-inoculated with 10µL of test organism and dried. Each carrier was subjected to alternating dry and wet wears until a total of 11 reinoculations and 12 wear cycles had been performed (Table 1 in the Protocol, pg 27 of 41).

Final Sanitizer Evaluation. Conducted at the completion of the wear cycles and reinoculations were identical to the Initial Sanitizer Evaluation. For each lot of the test surface, per microorganism, four carriers and four control surface carriers (per microorganism) will be inoculated at staggered intervals with 0.01 mL of the prepared final sanitizer inoculum using a calibrated pipette. The inoculum will be spread to within approximately 1/8th inch of the edge of the carrier and the carriers will be allowed to dry for 30-40 minutes at 35-37°C. Immediately after drying, the 2 hour contact time will begin at ambient temperature, after which each carrier will be transferred to ajar containing 30 mL of neutralizer at the appropriate staggered intervals. Each jar was subsequently sonicated for 20±2 seconds. The samples were then mixed on an orbital shaker for 3-4 minutes at 250 rpm. Serial dilution were then prepared using sterile deionized water. Duplicate 1.0 mL aliquots from each jar/dilution (10^0 – 10^{-2}) for the test carriers and (10^2 – 10^{-4}) for the control carriers were plated using TSA pour plates. *S. aureus* plates were incubated for 48±4 hours at 35-37°C. *E. aerogenes* plates were incubated for 48±4 hours at 25-30°C.

Controls included those for purity, sterility, inoculum confirmation counts, viability, neutralizer effectiveness, and microorganism confirmation.

6. **MRID No. 495658-12, "Efficacy Evaluation of Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces - Supplemental," using LuminOre Copper/Nickel by Angela Hollingsworth. Study Completion Date: February 4, 2015. Laboratory Project Identification Number: 872-112.**

The product was tested against *Pseudomonas aeruginosa* (ATCC# 15442), Methicillin Resistant *Staphylococcus aureus* (ATCC# 33592) and *Escherichia coli* O157:H7 (ATCC# 35150). Two lots (Lot Nos. 092314A and 092414A) of the product, LuminOre Copper/Nickel were tested using Protocol No. LUM.6a.06.16.14 (copy provided). A control sample, designated as Non Treated Coupons and assigned DS No. E532, was provided and included in the test system. The test system included 4 carrier replicates/lot and 8 control carrier replicates per test organism (4 initial carriers and 4 final carriers). Organic soil described as 0.25 mL of heat-inactivated fetal bovine serum plus

0.05 mL of Triton X-100 solution added to 4.70 mL of the bacteria suspension per 5 mL to yield at 5% FBS and 0.01% Trition X-100 challenge.

Initial Sanitizer Test. Each lot of the test surface carrier and control was inoculated with 10 µL of the prepared initial sanitizer inoculum. Carriers were allowed to dry for 30-40 minutes at 36°C at 35-37% relative humidity. Immediately after drying, the 120 minute contact time was initiated. At the conclusion of the contact time, each carrier was transferred to a jar containing 30 mL of neutralizer at the appropriate staggered intervals. Each jar was subsequently sonicated for 20±2 seconds. The samples were then mixed on an orbital shaker for 3-4 minutes at 250 rpm. Serial dilution were then prepared using sterile deionized water. Duplicate 1.0 mL aliquots from each jar/dilution (10^0 – 10^{-2}) for the test carriers and (10^2 – 10^{-4}) for the control carriers were plated using TSA pour plates. All test plates were incubated for 48±4 hours at 35-37°C.

Simulated Wear and Reinoculation. Prior to inoculation, the abrasion tester was set to a speed of 2.25 –2.50 for total surface contact time of approximately 4-5 seconds for one complete cycle. The speed was measured with a stopwatch, and the machine's cycle was calibrated by adjusting the number counter to 1, 5, 10, and 20 and verifying cycle time. It will be set so that one pass on the abrasion tester with the surfaces is equal to a contact time of approximately 2 seconds. A wear cycle was identified as one pass to the left and a return pass to the right on the Gardner scrubber with an abrasion boat fitted with a foam liner and dry cotton cloth. The weight of the fully assembled weight boat was determined to be 1084 ± 1g prior to use. For each lot of the test surface, per microorganism, four carriers will be inoculated at staggered intervals with 0.01 mL of the prepared simulated wears inoculum using a calibrated pipette. The inoculum will be spread to within approximately 1/8th inch of the edge of the carrier and the carriers will be allowed to dry for 30-40 minutes at 35-37°C. These inoculation and drying procedures will be designated as "reinoculated and drying." To initiate the wear cycles, each carrier was subjected to a dry wear cycle using the Gardco Washability and Wear Tester and the fully assembled wieght boat. Fifteen (15) minutes after the initial wear cycle, each carrier was re-inoculated and dried as previously described. Each carrier was then subjected to a wet wear cycle using the Gardco Washability and Wear Tester and the fully assembled wieght boat. The fully assembled weight boat was sprayed for one second with sterile deionized water using a Preval sprayer from a distance of 75±1 cm for not more than one second. At least 15 minutes after the secondary wear cycle, each carrier was re-inoculated with 10µL of test organism and dried. Each carrier was subjected to alternating dry and wet wears until a total of 11 reinoculations and 12 wear cycles had been performed (Table 1 in the Protocol, pg 26 of 39).

Final Sanitizer Evaluation. Conducted at the completion of the wear cycles and reinoculations were identical to the Initial Sanitizer Evaluation. For each lot of the test surface, per microorganism, four carriers and four control surface carriers (per microorganism) will be inoculated at staggered intervals with 0.01 mL of the prepared final sanitizer inoculum using a calibrated pipette. The inoculum will be spread to within approximately 1/8th inch of the edge of the carrier and the carriers will be allowed to dry for 30-40 minutes at 35-37°C. Immediately after drying, the 2 hour contact time will begin at ambient temperature, after which each carrier will be transferred to ajar containing 30 mL of neutralizer at the appropriate staggered intervals. Each jar was subsequently sonicated for 20±2 seconds. The samples were then mixed on an orbital shaker for 3-4 minutes at 250 rpm. Serial dilution were then prepared using sterile deionized water. Duplicate 1.0 mL aliquots from each jar/dilution (10^0 – 10^{-2}) for the test carriers and (10^2 –

10^{-4}) for the control carriers were plated using TSA pour plates. All test plates were incubated for 48±4 hours at 35-37°C.

Controls included those for purity, sterility, inoculum confirmation counts, viability, neutralizer effectiveness, and microorganism confirmation.

V SUMMARY OF RESULTS

Copper Enhanced Hard Surfaces as a Sanitizer

MRID Number	Organism	Lot No.	Average CFU/carrier	Average Organism Recovered (CFU/carrier)	Percent Reduction
495658-07	*Staphylococcus aureus*	092314A	5.4×10^5	<6.8	>99.9
		092414A		$<1.0\times10^0$	>99.9
		092414B		<8.8	>99.9
	Enterobacter aerogenes	092314A	1.3×10^6	230	>99.9
		092414A		408	>99.9
		092414B		528	>99.9
495658-08	*Pseudomonas aeruginosa*	092314A	5.7×10^6	1012	>99.9
		092414A		760	>99.9
	Staphylococcus aureus (MRSA)*	092314A	1.6×10^6	144	>99.9
		092414A		894	>99.9
	Escherichia coli O157:H7	092314A	3.1×10^6	464	>99.9
		092414A		536	>99.9

* Methicillin Resistant

Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as Sanitizer

MRID Number	Organism	Contact Time	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495658-09	*Staphylococcus aureus*	2 Hours	092314A	1.3×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
			092414B		$<1.0\times10^0$	>99.9
		6 Hours	092314A	2.4×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
			092414B		$<1.0\times10^0$	>99.9
		12 Hours	092314A	4.0×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
			092414B		$<1.0\times10^0$	>99.9
		18 Hours	092314A	5.4×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
			092414B		$<1.0\times10^0$	>99.9
		24 Hours	092314A	5.6×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
			092414B		$<1.0\times10^0$	>99.9

Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as Sanitizer

MRID Number	Organism	Contact Time	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495658-09	*Enterobacter aerogenes*	2 Hours	092314A	7.5×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
			092414B		$<1.0\times10^0$	>99.9
		6 Hours	092314A	1.3×10^6	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
			092414B		$<1.0\times10^0$	>99.9
		12 Hours	092314A	2.3×10^6	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
			092414B		$<1.0\times10^0$	>99.9
		18 Hours	092314A	1.6×10^6	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
			092414B		$<1.0\times10^0$	>99.9
		24 Hours	092314A	1.3×10^6	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
			092414B		$<1.0\times10^0$	>99.9

Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as Sanitizer

MRID Number	Organism	Contact Time	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495658-10	*Pseudomonas aeruginosa*	2 Hours	092314A	4.4×10^5	446	>99.0
			092414A		322	>99.9
		6 Hours	092314A	4.8×10^5	240	>99.9
			092414A		254	>99.9
		12 Hours	092314A	8.4×10^4	$<1.0\times10^0$	>99.9
			092414A		148	>99.0
		18 Hours	092314A	1.1×10^6	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
		24 Hours	092314A	9.2×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9

Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as Sanitizer

MRID Number	Organism	Contact Time	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495658-10	*Staphylococcus aureus* (MRSA)* *Methicillin Resistant	2 Hours	092314A	3.9×10^5	64	>99.9
			092414A		100	>99.9
		6 Hours	092314A	9.0×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
		12 Hours	092314A	6.8×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
		18 Hours	092314A	3.1×10^6	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
		24 Hours	092314A	9.1×10^6	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9

Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as Sanitizer

MRID Number	Organism	Contact Time	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495658-10	*Escherichia coli* O157:H7	2 Hours	092314A	8.9×10^5	302	>99.9
			092414A		252	>99.9
		6 Hours	092314A	1.5×10^6	$<1.0\times10^0$	>99.9
			092414A		<8.4	>99.9
		12 Hours	092314A	7.9×10^5	<12.8	>99.9
			092414A		$<1.0\times10^0$	>99.9
		18 Hours	092314A	2.4×10^6	<44.8	>99.9
			092414A		$<1.0\times10^0$	>99.9
		24 Hours	092314A	1.7×10^6	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9

Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces

MRID Number	Organism	Evaluation	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495658-11	*Staphylococcus aureus*	Initial	092314A	1.3×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
			092414B		$<1.0\times10^0$	>99.9
		Final	092314A	1.7×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
			092414B		$<1.0\times10^0$	>99.9

Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces

MRID Number	Organism	Evaluation	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495658-11	*Enterobacter aerogenes*	Initial	092314A	9.1×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
			092414B		$<1.0\times10^0$	>99.9
		Final	092314A	2.2×10^6	<155.5	>99.9
			092414A		<166.8	>99.9
			092414B		<432.8	>99.9

Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces

MRID Number	Organism	Evaluation	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495658-12	*Pseudomonas aeruginosa*	Initial	092314A	1.1×10^6	537.5	>99.9
			092414A		327.5	>99.9
		Final	092314A	1.4×10^6	<105.8	>99.9
			092414A		<133.3	>99.9

Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces

MRID Number	Organism	Evaluation	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495658-12	*Staphylococcus aureus* (MRSA)* *Methicillin Resistant	Initial	092314A	4.9×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9
		Final	092314A	5.6×10^5	$<1.0\times10^0$	>99.9
			092414A		$<1.0\times10^0$	>99.9

Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces

MRID Number	Organism	Evaluation	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495658-12	*Escherichia coli* O157:H7	Initial	092314A	1.1×10^6	<98	>99.9
			092414A		<215.5	>99.9
		Final	092314A	8.0×10^5	<90.8	>99.9
			092414A		$<1.0\times10^0$	>99.9

VI CONCLUSIONS

1. The label claims the product continuously reduces bacteria [sic] contamination, achieving 99.9% reduction within 2 hours of exposure. This claim is acceptable as it is supported by the submitted data. Change "bacteria" to adj. form – bacterial.

2. The label claims that the product kills greater than 99.9% of Gram-negative and Gram-positive bacteria within 2 hours of exposure. This claim is acceptable as it is supported by the submitted data.

3. The label claims that the product delivers continuous and ongoing antibacterial action, remaining effective in killing greater than 99.9% of bacteria within 2 hours.

This claim should be clarified to distinguish between continuous reduction (kill requirement of at least 90% reduction over 24 hours) and surface as a sanitizer (kill requirement of at least 99.9% over 2 hours).

4. The label claims that the product kills greater than 99.9% of bacteria within 2 hours and continues to kill 99% of bacteria even after repeated contaminations. This claim is acceptable as it is supported by the submitted data.

Label Comments:

- Claims are limited to indoor (i.e., hard, non-porous) surfaces where cleaning practices are consistent. All "Product is for indoor use only where cleaning practices are consistent."
- Pg. 3: Remove reference to "knurled" knobs.

Important Note: This product registration WILL require additional efficacy testing pending finalization of the copper surface protocol(s) by the Agency.