89016-5 9/26/2012 1/13

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:
x Registration
__ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
89016-5	SEP 26 2012

Term of Issuance: Unconditional

Name of Pesticide Product: LAG 5

Name and Address of Registrant (include ZIP Code):

Aurubis Buffalo, Inc.
P. O. Box 981
Buffalo, New York 14240

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration Number 89016-5."

Signature of Approving Official:

M Swindell

Marshall Swindell
Product Manager-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date: SEP 26 2012

EPA Form 8570-6

The Confidential Statement of Formula dated June 6, 2012, is acceptable.

The following are a listing of Conditions of Registration for Antimicrobial Copper Alloy registrations and associated labeling issues:

Condition 1

CDA will prepare and implement an Antimicrobial Copper Alloy Stewardship Plan ("the Plan") designed to support the responsible use of antimicrobial copper products. The Plan will be submitted for EPA review and approval within two months after the registration date. If EPA determines at any time after 18 months following registration that the Plan is not being adequately or timely implemented or that implementation of the Plan is not effectively ensuring the proper sale, distribution, or use of antimicrobial copper alloy products, the registration may be automatically cancelled by the Agency by order with no opportunity for a hearing but only after notification to the Registrant and an opportunity to meet with the Director of the Office of Pesticide Programs.

The Plan will include, at a minimum, the following elements:

(a) Outreach to the infection control community, including:

(i) A goal of educating and reinforcing, for infection control professionals and other product users, the proper use of Antimicrobial Copper Alloys.

(ii) Written (including electronic) communications directed to associations of infection control professionals, including at the least APIC, ASHES, and any other relevant organizations identified by CDA or EPA, and State Departments of Health.

(iii) Outreach communications will be sent within six months after the date of registration and within one year after the date of registration, and then annually thereafter on the anniversary of the date of the registration unless more frequent outreach is deemed necessary.

(iv) The content of the outreach communications will include statements explaining the registered claims and applications of Antimicrobial Copper Alloys, as well as their proper use. The communications also will inform the recipients about (1) the Antimicrobial Copper Alloy Working Group (see below) and invite their participation; (2) other sources of information on Antimicrobial Copper Alloys, including the Stewardship Website (see below). Additional content of outreach efforts will be developed as part of the Working Group activities.

(b) Development of a Stewardship Website ("the Website") under the auspices of the Copper Development Association ("CDA").

(i) The Website will serve as a resource for conveying accurate information to the public about the efficacy and proper use of Antimicrobial Copper Alloys.

(ii) The Website will include information on proper labeling and claims (including advertising); supporting science; applications; maintenance; and federal and state regulations and statutory requirements.

(iii) A question and answer or Frequently Asked Questions (FAQs) section will be incorporated to address common issues or questions raised with regard to Antimicrobial Copper Alloys.

(iv) The Website also will serve as a forum to correct any false or misleading third party statements or publications, including scientific papers, concerning Antimicrobial Copper Alloys. Any such false or misleading third party statements or publications will be corrected promptly after CDA or any member of CDA becomes aware of such and the responsive Website update will be incorporated promptly thereafter. CDA shall inform EPA within 30 calendar days following its receipt of any such false or misleading third party statements or publications and at that same time provide the Agency with a copy of such statement or publication along with a hard copy of the Website entry correcting such statement or publication.

(v) Links will be arranged and established by CDA between the Stewardship Website and the websites of appropriate infection control organizations, including but not limited to APIC and ASHES.

(c) Establishment of an Antimicrobial Copper Alloy Working Group ("the Working Group").

(i) Invited participants will include alloy manufacturers, component makers, and representatives from the infection control community, including appropriate trade associations (*e.g.*, APIC and ASHES) and State Departments of Health.

(ii) The Working Group will meet at least twice a year, either in person or by live video conferencing (WEBEX) or teleconferencing.

(iii) The Working Group will serve as a forum to expand educational efforts, develop outreach communications, and address any questions or concerns from the public and infection control community.

(iv) CDA shall provide EPA with minutes of any such meetings within 60 days of the end of any such meeting.

Condition 2

For at least the first 24 months after registration or until the Agency terminates this condition, whichever is later, the CDA will submit to EPA sample advertising materials. Advertising materials will be representative of advertisements intended for use in the marketplace.

3. Submit three (3) copies of the final printed label prior to releasing this product for sale.

A stamped copy of the label is enclosed for your records.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) or as may be deemed appropriate by the Agency, as provided for in Condition 1. Your release for shipment of the product constitutes acceptance of these conditions.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Branch I
Antimicrobials Division (7510P)

Enclosure: (Stamped Labeling)

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LAG 5
ANTIMICROBIAL COPPER ALLOYS AND ASSOCIATED FABRICATED PRODUCTS MASTER LABEL

The Master Label consists of the label that will accompany the Antimicrobial Alloys and a label that will accompany each product fabricated using a registered alloy from LAG 5.

[Alloy Label – Front Panel]

LAG 5
AND ASSOCIATED FABRICATED PRODUCTS

Active Ingredient:	
Copper	66.5%
Other	33.5%
Total	100%

EPA Registration No. 89016-L
EPA Establishment No. *****

Made in the United States by
Aurubis Buffalo, Inc.
P.O. Box 981
Buffalo, New York 14240

Net Weight: XXX lbs XXX ounces of LAG 5

ACCEPTED
with COMMENTS
in EPA Letter Dated:
SEP 26 2012
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 89016-5

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

LAG 5

These alloys are only intended for the manufacture and fabrication of touch surface components for use in hospitals, healthcare facilities, and various public, commercial, and residential buildings. [The claims listed on the attached fabricated product label may be made in connection with the marketing and sale of LAG 5 Antimicrobial Copper Alloys and fabricated products made from LAG 5 under EPA Registration Number 89016-L.]

A list of components that may be fabricated out of LAG 5 Antimicrobial Copper Alloys is specified below. LAG 5 Alloys are not approved for direct food contact or food packaging uses.

Touch Surface Components

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

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- 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.

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- 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

ACCEPTED
with COMMENTS
In EPA Letter Dated:

SEP 26 2012

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No 89016-5

Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- ATM machines: keys, housing
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- Soap dispenser (wall mounted): push bar and dispenser itself
- Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Light switches, switch plates
- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack

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- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Badge clips
- Name tags
- Vending machines (non-food contact only)
- Window sills
- Electrical wallplates
- Clip boards
- Office supplies: paper clips, staplers, tape dispensers

Residential Buildings (including homes, apartments, apartment buildings and other residences)

- 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)
- Bedrails, footboards
- Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Showerheads
- Countertops and tabletops
- 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
- Light switches, switch plates
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)

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- Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television remote
- Cup Holder
- Toothbrush holder
- Soap holder
- Magazine rack
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Window sills
- Electrical wallplates
- Baby cribs: rails, fittings, brackets, supports
- Bowl stands
- Office supplies: paper clips, staplers, tape dispensers
- Monitor (television, computer, etc.) housing

Mass Transit Facilities

- Handrails
- Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- Grab bars and handles
- Tiles: wall, floor, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- Signage
- Vending machines (non-food contact only)

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring
- Chapel pews
- Eye glass frames and protective eye wear
- Pens
- Combs
- Ashtrays

Do not wax, paint, lacquer, varnish, or otherwise coat touch surfaces.

LAG 5 – Fabricated Products

ACCEPTED
with COMMENTS
In EPA Letter Dated:
SEP 26 2012
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg No. 89016-5

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The LAG 5 fabricated products listed above may be sold and distributed under EPA Registration Number 89016-L. Products fabricated with LAG 5 must bear the EPA approved fabricated product label [below] with one or more of the listed claims.

STORAGE AND DISPOSAL

Dispose of excess by recycling.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
SEP 26 2012
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 89016-5

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ANTIMICROBIAL COPPER ALLOYS - GROUP V

Fabricated Product Label

FRONT

[This (touch surface) (product)] made from

LAG 5

Active Ingredient:
Copper 66.5%
Other..... ... 33.5%
[Total 100.0%]
See [Back/Side Panel][Insert] for Directions for Use
Net Weight: XXX lbs XXX ounces of LAG 5

BACK

LAG 5

Laboratory testing has shown that when cleaned regularly this surface:
- Continuously reduces bacteria* contamination, achieving 99.9% reduction within 2 hours of exposure.
- Kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within 2 hours of exposure.
- Delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours.
- Kills greater than 99.9% of bacteria* within two hours and continues to kill 99% of bacteria* even after repeated contaminations.
- Helps inhibit the buildup and growth of bacteria* within 2 hours of exposure between routine cleaning and sanitizing steps.
- [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)*.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Proper Care and Use. Clean and sanitize according to standard practice. Healthcare 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.

Not approved for direct food contact or food packaging uses.

[Items exposed to outdoor environmental conditions are not representative of indoor laboratory test conditions, and, therefore, may impart reduced efficacy if not cleaned when visibly soiled.]

STORAGE AND DISPOSAL

Dispose of by recycling or put in trash.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

EPA Reg. No. 89016-L EPA Est. No. [Product Manufacturer Number] 89016-XX-XXX
Manufactured by: [Product Manufacturer Company Name and Address]
Aurubis Buffalo, Inc. P.O. Box 981, Buffalo, New York 14240

ACCEPTED
with COMMENTS
In EPA Letter Dated:
SEP 26 2012
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 89016-5

LAG 5 (EPA Reg. No. 89016-L)
Master Label version dated June 8, 2012

[Optional Logo for Use with Alloy Label or Fabricated Product Label]

Antimicrobial Copper