09/20/2012



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

# OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SEP 2 0 2012

Mr. Rich Pratt Director of Marketing for, PMX Industries, Inc. 5300 Willow Creek Drive Cedar Rapids, IA 52404

Mail to: Mr. Micah T. Reynolds 1150 18<sup>th</sup> Street, NW, Suite 1000 Washington, D.C. 20036

Subject: MicroGuard II EPA Registration Number 85290-2 Your Notification Dated August 20, 2012 EPA Received Date August 21, 2012

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add an optional marketing logo for use on the copper alloy product labeling and/or fabricator product labeling, is acceptable.

The notification has been made part of the permanent file.

If you have questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,

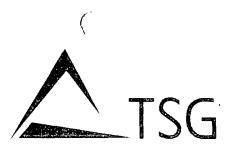
Marshall Swindell

Product Manager 33<sup>(</sup> Regulatory Management Branch I Antimicrobial Division(7510P)

				Form Approved. OMB No. 2070-0060. Approval expires 05-31-98				
	united States United States Environmental Protection Washington, DC 20460			Agency		gistration nendment her	OPP Identifier Number	
Application for Pesticide – Section I								
1. Company/Product Number			2. EPA Product Manager				3. Proposed Classification	
85290-2 4. Company/Product (Name)			Marshall Swindell			vinaeli	None Restricted	
MicroGuard II				33				
5. Name And Address Of Applicant (Include ZIP Code) <b>PMX Industries, Inc.</b> <b>5300 Willow Creek Drive, SW</b> <b>Cedar Rapids, Iowa 52404</b> Check if this is a new address			6. Expedited Review. In accordance with FIFRA Section 3(c)(3)     (b)(i), my product is similar or identical in composition and labeling     to:     EPA Reg. No  Product Name					
Section II								
<ul> <li>Amendment – Explain below.</li> <li>Resubmission in response to Agency letter dated</li> <li>Notification – Explain below.</li> </ul>				<ul> <li>Final Printed labels in response to Agency letter dated</li></ul>				
Submission of Label Notification to add marketing logo. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Please confirm receipt with Micah Reynolds: <u>mreynolds@tsgusa.com</u> , phone (202) 828-8967, or fax (202) 872-0745. Section III 1. Material This Product Will Be Packaged In:								
Child Resistant Packaging Yes* No * Certification must be submitted	Yes         Image: Constraint of the second sec			/es			ntainer tal istic iss per	
be Subinitied						Oth	ner (Specify)	
3. Location of Net Contents Information       4. Size(S) R         Label       Container			etail Container 5. Lo			On Labe	Cation of Label Directions On Label On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product Lithographed Pager glued Other Stenciled								
Section IV								
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)         Name       Title       Telephone No. (Include Area Code)         Micah T. Reynolds, Technology Sciences Group, Inc.       Regulatory Consultant       (202) 828-8967							one No. (Include Area Code)	
Certification         I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.         I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.       6. Date Application         I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of       6. Date Application         Bornulatory       Consultant to PMY Industring								
4. Typed Name Micah T. Reynolds			5. Date	August 20, 2012				
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EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

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Technology Sciences Group Inc. 1150 18<sup>th</sup> Street, Suite 1000 Washington, DC 20036 Direct: (202) 828-8967 Fax: (202) 872-0745 E-Mail: MReynolds@TSGUSA.com

Micah T. Reynolds Regulatory Consultant

August 20, 2012

PMX Industries, Inc. Label Notification for MicroGuard II; EPA Reg. No. 85290-2

Mr. Marshall Swindell, PM-33 Antimicrobials Division (7504P) Office of Pesticide Programs U.S. Environmental Protection Agency Document Processing Center Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, Virginia 22202

Dear Mr. Swindell:

Technology Sciences Group, Inc., on behalf of PMX Industries, Inc., is submitting the enclosed label notification to add an optional marketing logo for use on the copper alloy product label and/or the fabricated product label. Conventionally, a redline version of the revised label (showing changes made) would be provided; however, since only the logo has been added (creating a ninth page of the label) with no other changes, a redline label was not produced. Please find enclosed the following documents supporting this notification:

- 1) Application for Notification (EPA Form 8570-1);
- 2) Three (3) copies of revised product labeling.

If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8967 or by e-mail at <u>mreynolds@tsgusa.com</u>.

Sincerely,

Regulatory Consultant to PMX Industries, Inc.

Enclosures

CC: R. Pratt (PMX Industries, Inc.)

**Washington, D.C.** 1150 18<sup>th</sup> St., NW, Suite 1000 Washington, D.C. 20036 Phone: (202) 223-4392 **California** 712 Fifth St., Suite A Davis, CA 95616 Phone: (530) 757-1245 Canada 275 Slater St., Suite 900 Ottawa, Ontario K1P 5H9 Phone: (613) 247-6285

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# MicroGuard II AND ASSOCIATED FABRICATED PRODUCTS MASTER LABEL

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

[Alloy Label – Front Panel]

# MicroGuard II AND ASSOCIATED FABRICATED PRODUCTS

Active Ingredient: Copper Other

91.3% 8.7%

100%

Total

EPA Registration No. 85290-2 EPA Establishment No. 85290-XX Made in the United States by: PMX Industries, Inc. 5300 Willow Creek Drive SW, Cedar Rapids, IA 52404

Net Weight: XXX lbs XXX ounces of MicroGuard II

Date Reviewed Reviewed By:



### **DIRECTIONS FOR USE**

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

#### MicroGuard II Antimicrobial Copper Alloys

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 MicroGuard II Antimicrobial Copper Alloys and fabricated products made from MicroGuard II Antimicrobial Copper Alloys under EPA Registration Number 85290-2.

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

#### **Touch Surface Components**

#### Healthcare Facilities

- o 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
- o 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

NOTIFICAT Date Reviewed: Fleviewed Bv:

#### MicroGuard II ... 'A Reg. No. 85290-2) Master Label version dated August 13, 2012

- $\circ$  Towel bars
- Showerheads
- Countertops and tabletops (non-food use only)
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Closures
- Vertical locking arms
- Vertical cover guards
- Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Instrument handles

Medical equipment knobs, pulls and handles for:

- Drug delivery systems
- Monitoring systems
- Hospital beds
- Office equipment
- Operating room equipment
- Stands and fixtures

Types of knobs: e.g., Prong, fluted, knurled, push/pull, T-handle, tapered, and ball knobs

- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- Pans (bed)
- Walkers, wheelchair handles, and tubular components
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise and rehabilitation equipment, handles, bars
- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Lighting products: X-ray illuminators, operating rooms, patient examination rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges)

 Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV poles

VOTIFICAL Date Reviewed: Fleviewed By:

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- Critical care cart: Table top, drawer, drawer pull, lock, copper wire baskets for storage of equipment and charts.
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- o Medical records: Chart holders, clipboards, filing systems
- Storage Shelving: wire shelving etc. for medical supplies
- Grab handles on privacy curtains
- o Lids of laundry hampers, trash canisters, and other containers
- o Bedside pitchers
- Closet rods and hangers
- o Television controls: knobs, buttons, remote
- o Monitor (television, computer, etc.) housing
- Cup Holder
- o Toothbrush holder
- Soap holder
- o Magazine rack
- o Signage
- Coat rack and hooks
- o Shower curtain rings
- Radiator cover
- o Bracelets
- o Pens
- o Badge clips
- Name tags
- Patient gown snaps
- o Window sills, pulls and locks
- o Electrical wallplates

#### Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- o ATM machines: keys, housing
- o 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
- o 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)
- o Light switches, switch plates

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• Lids of laundry hampers, trash canisters, and other containers

- o Magazine rack
- o Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- o Bracelets
- Badge clips
- o 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)
- o Bedrails, footboards
- o Handrails
- o 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
- o 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)

o 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)

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

### Mass Transit Facilities

- o Handrails
- Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- o Grab bars and handles
- Tiles: wall, floor, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- o 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
- o Chapel pews
- Eye glass frames and protective eye wear
- o Pens
- o Combs
- o Ashtrays

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

NOTIFICAT Date Reviewed: Reviewed By:

MicroGuard II A Reg. No. 85290-2) Master Label version dated August 13, 2012

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### MicroGuard II – Fabricated Products

The MicroGuard II fabricated products listed above may be sold and distributed under EPA Registration Number 85290-2. Products fabricated with MicroGuard II Antimicrobial Copper Alloys 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.

NOTIFICAL Date Reviewed: Fieviewed By:

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#### MicroGuard II ... 'A Reg. No. 85290-2) Master Label version dated August 13, 2012

## MicroGuard II Fabricated Product Label

## BACK

#### MicroGuard II

- 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 necession for good sandation and to assure the effective antibacterial performance of this surface. Cleaning agents typically used for traditional hard, non-porous touche 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. 85290-2 BPA Est. No. [Product Manufacturer Number]- 85290-XX] Manufactured by: [Product Manufacturer Company Name and Address] PMX Industries, Inc., 5300 Willow Creek Drive SW, Cedar Rapids, IA 52404

NOTIFICAT Date Reviewed

Active Ingredient:

[Total

MicroGuard II

Use

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

Net Weight: XXX lbs XXX ounces of

Other..... 8.7%

MicroGuard II

See [Back/Side Panel][Insert] for Directions for

100.0%]

FRONT

MicroGuard II (EPA Reg. No. 85290-2) Master Label version dated August 13, 2012

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

# Antimicrobial Copper

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NOTIFICATION Date Reviewed: K.Lenty