85290-4

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 IV EPA Registration Number 85290-4 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,

11 Marshall Swindell

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

 $\sim$ 

(

		(					(		
Please read instructions on i	reverse side before completir	ig form		Forr	n Approve	d OMB	No 2070 0		al expires 05 31 98 Itifier Number
SEPA United States Environmental Protection Washington DC 2046			ction Age	ency			ation ment		
		Applicat	ion for P	esticide – Se					
1 Company/Product Nur	nber 85290-4			2 EPA Product N	•	www.el		B Proposed C	Classification
4 Company/Product (Na			Marshall Swindell				X None	Restricted	
MicroGuard IV				33					
5 Name And Address Of Applicant (Include ZIP Code)				6 Expedited Review In accordance with FIFRA Section 3(c)(3)					
PMX Industries, Inc				<ul> <li>(b)(i) my product is similar or identical in composition and labeling to</li> </ul>					
5300 Willow Cre				EPA Reg No					
Cedar Rapıds, I	owa 52404			Product Name					
Check if th	us is a new address			Product Name	<u> </u>				
			Sec	tion II					
Amendment – Expla	ain below			Final Print	ed labels ii	n respor	nse to		
Resubmission in res	sponse to Agency letter d	ated		Agency letter dated					
Notification – Explai				Me Too	Application	1			
				Uther – E	kplain Belo	w			
•	ubject to enforcement actions in the second se		reynolds@			(202) 8	328-8967	, or fax (20	02) 872 0745
1 Material This Product V	Vill Be Packaged In								
Child Resistant Packagir			Water S	oluble Packaging		2 Tv	pe of Conta	iner	
Yes	Yes			Yes Metal					
No	No No			)	Plastic			C	
* Certification mus	t If Yes	No per	If Yes	N	o per	<b>1</b>  -	Glass		
be submitted	Unit Packaging wgt	Container	Unit Pad	ckaging wgt C	ontainer		Paper	(Specify)	
3 Location of Net Conter	ts Information	4 Size(S) R	etail Contain	er	5	Locatio	n of Label D		
	Container						On Label		una product
6 Manner in Which Label is Affixed to Product			lued						
		Stencile		ion IV	<u> </u>		<u>.                                    </u>	· · · ·	
1 Contact Point (Comple	te items directly below for	ridentification			necessary	/ to pro	cess this ap	plication )	······································
Name						Telephon	phone No (Include Area Code)		
Micah T Reynolds Technology Sciences Group Inc			Regulatory Consultant (202) 820			8 8967			
Certify that the statements I have made on this form and all ai I acknowledge that any knowingly false or misleading stateme both under applicable law							6 Date A Receive (\$		
2 Signature			3 Title Regulatory Consultant to PMX Industries, Inc						
4 Typed Name Micah T Reynolds			5 Date August 20, 2012						

EPA Form 8570 1	(Rev	8 94)	Previous editions	are obsolete



**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 IV, EPA Reg No 85290-4

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 mreynolds@tsgusa.com

Sincerely

Regulatory Consultant to PMX Industries Inc

Enclosures

CC R Pratt (PMX Industries Inc)

 Washington
 D
 C

 1150
 18 <sup>h</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

275 Stater St. Suite 900 Ottawa Ontario K1P 5H9 Phone (613) 247 6285

2

## MICTOGUATH IV AND ASSOCIATED FABRICATED PRODUCTS MASTER LABEL

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

#### [Alloy Label – Front Panel]

### MICTOGUARD IV AND ASSOCIATED FABRICATED PRODUCTS

Active Ingredient Copper	73 0%
Other	27 0%
Total	100%

EPA Registration No 85290-4 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 IV



#### **DIRECTIONS FOR USE**

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

#### MicroGuard IV 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 IV Antimicrobial Copper Alloys and fabricated products made from MicroGuard IV Antimicrobial Copper Alloys under EPA Registration Number 85290-4

A list of components that may be fabricated out of MicroGuard IV Antimicrobial Copper Alloys is specified below MicroGuard IV 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
- 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
- o 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

Date Reviewed **Reviewed By** 

#### MicroGuard IV ( A Reg No 85290-4) Master Label version dated August 13, 2012

- o Towel bars
- o Showerheads
- Countertops and tabletops (non-food use only)
- o Hinges, locks, latches, and trim
- o Door stops, door pulls, and protector guards
- o Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- o Closures
- o Vertical locking arms
- o Vertical cover guards
- o Protection bars
- o Light switches, switch plates
- o Visitor chairs armrests, metal frames
- o 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)
- o Floor tiles
- o Ceiling tiles (non-porous)
- o 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 eg, Prong, fluted, knurled, push/pull, T-handle, tapered, and ball knobs

- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- o Pans (bed)
- o Walkers, wheelchair handles, and tubular components
- o 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
- o 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

NOTIFICATION Date Reviewed

- 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
- o Closet rods and hangers
- Television controls knobs, buttons, remote
- Monitor (television, computer, etc.) housing
- o Cup Holder
- o Toothbrush holder
- o Soap holder
- o Magazine rack
- o Signage
- Coat rack and hooks
- Shower curtain rings
- o Radiator cover
- Bracelets
- o Pens
- o Badge clips
- o Name tags
- o Patient gown snaps
- o Window sills, pulls and locks
- o Electrical wallplates

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

- o Shopping cart handles, child seats, handrails
- o Cash registers housing, keypads
- 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
- o Paper towel dispensers Housing itself, (turn) handle, (push) handle
- o Soap holder
- o 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)
- o Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- o Light switches, switch plates

NOTIFICATION Date Reviewed 1/20/12

- o Lids of laundry hampers, trash canisters, and other containers
- o Magazine rack
- o Signage
- o Coat rack and hooks
- o Shower curtain rings
- o Radiator cover
- o Bracelets
- o Badge clips
- o Name tags
- Vending machines (non-food contact only)

(

- o Window sills
- o Electrical wallplates
- o Clip boards
- Office supplies paper clips, staplers, tape dispensers

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

- Kıtchen surfaces (non-food contact only) table tops, counter tops, handles (mıcrowave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- o Bedrails, footboards
- Handraıls
- o Stair rails
- o Door push plates
- o Sinks spigots, drains, sinks themselves
- o 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
- o 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
- o Light switches, switch plates
- o Thermostat covers, control knobs and wheels
- o Telephone handsets and surfaces (housings), keypad
- o Floor tiles
- o Ceiling tiles (non-porous)
- Wall tiles
- Computer keyboards keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- o Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- o Jalousie Windows (crank)

NOTIFICATION Date Reviewed Affective Reviewed By

#### MicroGuard IV A Reg No 85290-4) Master Label version dated August 13, 2012

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

#### **Mass Transit Facilities**

- o Handraıls
- 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
- 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
- Chapel pews
- o Eye glass frames and protective eye wear
- o Pens
- o Combs
- o Ashtrays

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

NOTHICALL Date Reviewed Z

11/13

#### MicroGuard IV - Fabricated Products

ĺ

The MicroGuard IV fabricated products listed above may be sold and distributed under EPA Registration Number 85290-4 Products fabricated with MicroGuard IV 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

AVO FIFICATION

#### MicroGuard IV Fabricated Product Label

#### BACK

#### FRONT

[This (touch surface) (product)] made from MicroGuard IV Active Ingredient Copper 73 0% Other 27 0% [Total 100 0%] See [Back/Side Panel][Insert] for Directions for Use Net Weight XXX lbs XXX ounces of MicroGuard IV

#### MicroGuard IV

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

NO ITFICA Date Reviewed

13/13

MicroGuard IV (EPA Reg No 85290-4) Master Label version dated August 13, 2012

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

# Antimicrobial Copper

(





9