

02/25/2010



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Akin Gump Strauss Hauer & Feld LLP
c/o for PMX Industries, Inc.
Robert S. Strauss Building
133 New Hampshire Ave, N.W.
Washington, DC 20036

Attention: Charles Franklin
Regulatory Manager

FEB 25 2010

Subject: Notification
MicroGuard IV
EPA Reg. No. 85290-4
Amendment Letter dated January 22, 2010

This will acknowledge receipt of your notification for the aforementioned product labels, submitted under the provisions of FIFRA Section 3(c) (9). Based on a review of the submitted material, the following apply:

- Minor corrections to the label

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

A handwritten signature in cursive script that reads "M Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

Print Form

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 85290-4	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) PMX Industries, Inc., MicroGuard IV	PM# Project Manager 33	
5. Name and Address of Applicant (Include ZIP Code) PMX Industries, Inc., 5300 Willow Creek Drive Cedar Rapids, IA 52404 <input type="checkbox"/> 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: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is a notification regarding several minor corrections to the MicroGuard IV label, Reg. No. 85290-4, to correct typographical errors in the current label per IV(A) of P.R. Notice 98.1, and to correct claims inconsistent with previously-approved changes made to the Master Registration, Reg. No. 82012-4. See Attachment A for the complete statement.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt. _____ No. per container _____		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container NA-no container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other Packaging _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Rich Pratt	Title Dir. Marketing and R&D	Telephone No. (Include Area Code) 319-431-4442
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 		
3. Title Director of Marketing and R&D		
4. Typed Name Rich Pratt		5. Date January 22, 2010

**AKIN GUMP
STRAUSS HAUER & FELD LLP**

Attorneys at Law

CHARLES L. FRANKLIN
202.887.4378/fax: 202.887.4288
clfrankin@akingump.com

January 26, 2010

VIA OVERNIGHT MAIL

Mr. Marshall Swindell
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code 7504P
Washington, DC 20460

Re: Notification of Minor Corrections to PMX MicroGuard IV™ Label

Dear Mr. Swindell:

On behalf of PMX Industries, Inc., Akin Gump Strauss Hauer & Feld, LLP submits the enclosed notification identifying minor corrections to the label for MicroGuard IV™, Reg. No. 85290-4, authorized under Sections II and IV of P.R. Notice 98.10. These changes are necessary to correct grammatical inconsistencies, redundancies, and omissions or inconsistencies with the Master Registration, Reg. No. 82012-4, held by the Copper Development Association (“CDA”). PMX is notifying EPA of the following corrections:

- 1) On Page five (5) of the MicroGuard IV™ Master Label, add the word “surfaces” after “MicroGuard IV™” in the sentence: “*MicroGuard IV™ surfaces continuously reduce bacterial* contamination, achieving a 99.9% Gram-positive bacteria* within two hours of exposure.*”
- 2) On Page five (5) of the MicroGuard IV™ Master Label, remove the words “Even after repeated wet and dry abrasions and re-contamination” from the sentence: “[*MicroGuard IV™ surfaces deliver continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within two hours, even after repeated wet and dry abrasion and re-contamination.*].”
- 3) On Page five (5) of the MicroGuard IV™ Master Label, remove the second appearance of the phrase “When cleaned regularly” from the sentence: “*Laboratory testing has shown that when cleaned regularly . . . [~~When cleaned regularly,~~ MicroGuard IV™ surfaces kill greater than 99.9% of bacteria* within two hours, and continue to kill more than 99% of bacteria* even after repeated contamination.*].”

AKIN GUMP
STRAUSS HAUER & FELD LLP

Attorneys at Law

Mr. Marshall Swindell
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4) On Page five (5) of the MicroGuard IV™ Master Label, remove the statement “*Nominal percentages for purposes of review and approval. Actual percentage of copper and other ingredients will be indicated on labels distributed with this product” from the label.

5) On Page five (5) of the MicroGuard IV™ Master Label, add the words “Net Contents:” to the label.

6) On Page ten (10) of the MicroGuard IV™ Master Label, under “Storage and Disposal,” replace the phrase “Antimicrobial Copper Alloys” with “MicroGuard IV™ surfaces.”

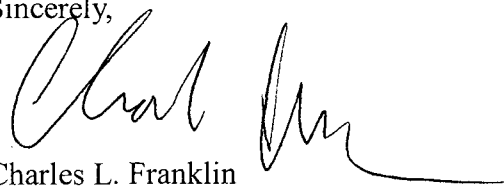
7) On Page ten (10) of the MicroGuard IV™ Master Label, under Warranty Statement, replace the phrase “Antimicrobial Copper Alloys” with “MicroGuard IV™ surfaces.”

As demonstrated above, these are minor corrections, and none has the potential to cause unreasonable adverse effects to the environment. In fact, these corrections will increase the consistency and understandability of PMX label. As such, in accordance with 40 C.F.R. § 152.46 and P.R. Notice 98.10, please find the following notification materials:

- This cover letter;
- One (1) EPA Notification Form 8570-C (Tab A);
- One (1) redline copy of the label, identifying all corrections (Tab B); and
- Two (2) clean copies of the corrected label (Tab C).

Thank you for your timely consideration of this submission. Please let me know if you have any questions.

Sincerely,



Charles L. Franklin

Enclosures

cc: Rich Pratt, PMX

MicroGuard IV™
Federal Master Label

Laboratory testing has shown that when cleaned regularly:

[MicroGuard IV™ surfaces continuously reduce bacterial* contamination, achieving 99.9% reduction within two hours of exposure.]

[MicroGuard IV™ surfaces kill greater than 99.9% of Gram-negative and Gram-positive bacteria* within two hours of exposure.]

[MicroGuard IV™ surfaces deliver continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within two hours.]

[MicroGuard IV™ surfaces kill greater than 99.9% of bacteria* within two hours, and continue to kill 99% of bacteria* even after repeated contamination.]

Deleted: , even after repeated wet and dry abrasion and re-contamination

Deleted: When cleaned regularly,

Deleted: more than

[MicroGuard IV™ surfaces help inhibit the buildup and growth of bacteria* within two hours of exposure between routine cleaning and sanitizing steps.]

* Testing demonstrates effective antibacterial activity against *Staphylococcus aureus*, *Enterobacter aerogenes*, Methicillin-Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* O157:H7, and *Pseudomonas aeruginosa*.

The use of a MicroGuard IV™ 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. The MicroGuard IV™ surface material has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

* * * * *

Active Ingredient:

Copper 73.0%
Other 27.0%
Total 100%

Net Contents: ****

Deleted: *Nominal percentages for purposes of review and approval. Actual percentage of copper and other ingredients will be indicated on labels distributed with this product. †

EPA Registration No. 85290-4

EPA Establishment No. 85290-IA-001

Manufactured by: PMX Industries, Inc, 5300 Willow Creek Dr, Cedar Rapids, IA 52404

DIRECTIONS FOR USE

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

[The directions in bracketed text below may be included in an insert. If so, there will be a statement to see the insert for additional directions for use of the product.]

[Directions for Use in the insert also may include installation and operation instructions, user manuals, and similar instructional materials appropriate for the end use product. No additional pesticidal claims will be made as part of these materials.]

Proper Care and Use of MicroGuard IV™: The use of MicroGuard IV™ does not replace standard infection control procedures and good hygienic practices. Antimicrobial MicroGuard IV™ surfaces must be cleaned and sanitized according to standard practice. Health 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.

MicroGuard IV™ surfaces may be subject to recontamination and the level of active bacteria at any particular time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order for the MicroGuard IV™ surface to have proper antimicrobial effect, the product must be cleaned and maintained according to the directions included on this label.

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

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of the MicroGuard IV™ surface. 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. [Normal tarnishing or wear of MicroGuard IV™ surfaces will not impair the antibacterial effectiveness of the product.]

This product can not be used for any direct food contact or food packaging uses.

[MicroGuard IV™ may be used in hospitals, other healthcare facilities, and various public, commercial, and residential buildings for the non-food contact surfaces listed below.] [The following statement will appear on the label if the use involves potential exposure to outdoor conditions: Surfaces that may be exposed to outdoor environmental conditions (e.g., handrails, shopping carts, child seats and ATM machines) are not representative of indoor laboratory test conditions, and therefore, may impart reduced efficacy if not cleaned when visibly soiled.]

Healthcare Facilities

- o Bedrails, footboards
- o Over-bed tables
- o Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)
- o Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- o Stair rails, handrails, tubular railing, and supports, rail fittings: T's, elbows and brackets
- o Bedrails, assistance rails,
- o 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)
 - o Equipment carts (horizontal surfaces, frames, handles)
 - o Door push plates, kick plates, mop plates, stretcher plates
 - o Sinks: spigots, drains, sinks themselves
 - o Faucet: handles, spigot, drain control lever
 - o Water fountains: bubbler head, drain strainer, handle
 - o Alcohol sanitizer dispenser, handle
 - o Paper towel holders, facial tissue holders, toilet paper holders
 - o Air hand dryer, controls and push buttons on air hand dryers
 - o Hydrotherapy tanks (whirlpool tanks):
 - shells, covers, headrests, drain fittings (outer surfaces without water contact)
 - o Door handles, doorknobs (outer touch surfaces)
 - o Grab bars in bathrooms showers and bathtubs
 - o Panic bars on emergency room doors
 - o Towel bars
 - o Showerheads
 - o 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
 - o 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
 - o Telephone handsets and surfaces (housings), keypad
 - o 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
 - o 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
 - o Intravenous (IV) poles, bases, hangers, clips
 - o Trays (instruments, non-food contact)
 - o Pans (bed)
 - o Walkers, wheelchair handles, and tubular components
 - o Computer keyboards: keys, housings, computer mouse surfaces
 - o Exercise and rehabilitation equipment, handles, bars
 - o Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
 - o Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
 - o 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)
 - o 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
 - o Critical care cart: Table top, drawer, drawer pull, lock, copper wire baskets for storage of equipment and charts.
 - o 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
- o Storage Shelving: wire shelving etc. for medical supplies
- o Grab handles on privacy curtains
- o Lids of laundry hampers, trash canisters, and other containers

Community Facilities (including various public and commercial buildings)

- o Shopping cart handles, child seats, handrails
- o Cash registers: housing, keypads
- o ATM machines: keys, housing
- o Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- o Ice and water dispensers (outer surfaces without water contact)
- o 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
- o Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- o Toilet paper dispenser (housing)
- o Windows (crank), Locking mechanism, pull handles
- o Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- o Jalousie Windows (crank)
- o Casement (cranks, levers, hinges)
- o Single and double-hung windows (locks and pulls)
- o Light switches, switch plates
- o Lids of laundry hampers, trash canisters, and other containers

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

- o 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
- o Door push plates
- o Sinks: spigots, drains, sinks themselves
- o Faucet: handles, spigot, drain control lever
- o Paper towel holders, facial tissue holders, toilet paper holders
- o Door handles, doorknobs (outer touch surfaces)
- o Grab bars in bathrooms showers and bathtubs
- o Towel bars
- o Showerheads
- o Countertops and tabletops
- o Hinges, locks, latches, and trim
- o Door stops, door pulls, and protector guards
- o Toilet and urinal hardware, levers, push buttons
- o 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)
- o Wall tiles
- o Computer keyboards: keys, housings, computer mouse surfaces
- o Exercise equipment, handles, bars
- o Windows (crank), Locking mechanism, pull handles
- o Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- o Jalousie Windows (crank)
- o Casement (cranks, levers, hinges)
- o Single and double-hung windows (locks and pulls)

- o Television control knobs and buttons
- o Lids of laundry hampers, trash canisters, and other containers

Other

- o Play area equipment (indoor only):
bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring

STORAGE AND DISPOSAL

MicroGuard IV™ should be disposed in a responsible manner, including recycling.

Deleted: Antimicrobial Copper alloys

WARRANTY STATEMENT

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

Deleted: Antimicrobial Copper

Deleted: alloys