

85290-5

10/31/2008

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Antimicrobials Division (7510C)  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460

EPA Reg. Number:  
85290-5

Date of Issuance:  
OCT 31 2008

Term of Issuance:  
Unconditional

Name of Pesticide Product:  
MicroGuard V

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

PMX Industries, Inc.  
5300 Willow Creek Drive  
Cedar Rapids, IA 52404

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 85290-5."

Signature of Approving Official:

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

Date:

OCT 31 2008

The following are a listing of Conditions of Registration for PMX Industries, Inc. registration and associated labeling issues:

### **Conditions 1**

CDA will prepare and implement an Antimicrobia 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 after 18 months following registration that 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 products 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). 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 that same time product 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) CDA will arrange for and establish links 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 Department 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 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.

The Confidential Statement of Formula dated July 10<sup>th</sup>, 2008, is acceptable.

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

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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

Sincerely,



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

Enclosure: (Stamped Labeling)

### MicroGuard V

Laboratory testing has shown that when cleaned regularly:

[Antimicrobial Copper Alloys continuously reduce bacterial\* contamination, achieving 99.9% reduction within two hours of exposure.]

[Antimicrobial Copper Alloys surfaces kill greater than 99.9% of Gram-negative and Gram-positive bacteria\* within two hours of exposure.]

[Antimicrobial Copper Alloys 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.]

[When cleaned regularly, Antimicrobial Copper Alloys surfaces kill greater than 99.9% of bacteria\* within two hours, and continue to kill more than 99% of bacteria\* even after repeated contamination.]

[Antimicrobial Copper Alloys 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 Copper Alloy 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 Copper Alloy surface material has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

\* \* \* \* \*

Active Ingredient:

Copper	66.5%#
Other	33.5%#
Total	100%

# Nominal percentages for purpose of review and approval. Actual percentage of copper and other ingredients will be indicated on labels distributed with the product.

EPA Registration No. \*\*\*\*

EPA Establishment No. \*\*\*\*\*

Manufactured by:

Net Contents: \*\*\*\*\*

**ACCEPTED**  
with **COMMENTS**  
EPA Letter Dated:

PMX Industries, Inc.  
5300 Willow Creek Dr.  
Cedar Rapids, IA 52404

OCT 31 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 85890-5