

43813-34

10/1/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OCT 1 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

William R. Goodwine
Janssen PMP, a Division of Janssen Pharmaceutica, N.V.
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Subject: Notification in Accordance with PR Notice 98-10
Bethoguard Biocide
EPA Registration Number: 43813-34
Application Dated: September 14, 2009
Receipt Date: September 16, 2009

Dear Mr. Goodwine:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 98-10, FIFRA section 3 (c) 9.

Proposed Notification:

Revise label per PR Notice 2007-4

General Comment:

Based on a review of the material submitted, the following comment applies.

The notification is acceptable.

Should you have any questions concerning this letter, please contact Lisa McKelvin by telephone at (703) 308-7496 or email address at mckelvin.lisa@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "ShaRon Carlisle".

ShaRon Carlisle
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

2090



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: 43813-34	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BETHOGUARD BIOCIDES	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Janssen PMP, a Division of Janssen Pharmaceutica, N.V. 1125 Trenton-Harbourton Road Titusville, NJ 08560-0200 <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: 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.)

"Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156, 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."

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
* Certification must be submitted	If "Yes" Unit Packaging wgt. No. per container.	If "Yes" Package wgt. No. per container.		<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input checked="" type="checkbox"/> Other (Specify) PLASTIC LINED FIBER DRUM	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55 & 110 LBS (25 & 50 Kg)		5. Location of Label Directions <input type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product			<input checked="" type="checkbox"/> Lithograph Paper glued Stenciled	<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name William R. Goodwine	Title Senior Director, Regulatory Affairs & Product Development	Telephone No. (Include Area Code) (609) 730-2607
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 <i>William R. Goodwine</i>	3. Title Senior Director, Regulatory Affairs & Product Development	
4. Typed Name William R. Goodwine	5. Date September 14, 2009	

BETHOGUARD™

Biocide For Material Preservation

NOTIFICATION
 Date Reviewed: 10/1/09
 Reviewed By:

ACTIVE INGREDIENT: (w/w)

BETHOXAZIN:

3-(Benzof[b]thiophen-2yl)-5,6-dihydro-1,4,2-oxathiazine, 4-oxide..... 96.6%

INERT INGREDIENTS: (w/w) 3.4%

TOTAL..... 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER


FIRST AID	
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center, or doctor, or 1-800-424-9300 immediately for treatment advice.
IF ON SKIN OR CLOTHING	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center, or doctor, or 1-800-424-9300 immediately for treatment advice.
IF SWALLOWED	Call a poison control center, or doctor, or 1-800-424-9300 immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center, or doctor, or 1-800-424-9300 immediately for treatment advice.
HOT LINE NUMBER 1-800-424-9300	
Have the product container with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

SEE OTHER PANEL FOR PRECAUTIONARY STATEMENTS

NET CONTENTS: 55 pounds (25 kilograms)

EPA REG. NO. 43813-34

EPA EST. NO. 43813-BL-02

 **JANSSEN PMP**
 a Division of Janssen Pharmaceutica NV.
 1125 Trenton-Harbourton Road
 Titusville, NJ 08560-0200

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**PRECAUTIONARY STATEMENT
HAZARDS TO HUMANS & DOMESTIC ANIMALS**

DANGER

Corrosive. Causes irreversible eye damage. Do not get in eyes, on skin or on clothing. Harmful if swallowed or inhaled. Avoid breathing dust. **Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.**

HANDLER PERSONAL PROTECTIVE EQUIPMENT

- When mixing, loading, or applying pesticide, and for routine cleaning or maintenance of equipment, wear protective eyewear (goggles, face shield or safety glasses), protective clothing (long sleeved shirt, long pants, socks, and safety shoes), chemical resistant gloves such as natural rubber, polyethylene or PVC and a dust filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N, R, P, or HE filter. Bystanders in close proximity to treatment areas during pesticide application/incorporation are also required to wear the respirator PPE cited above.
- Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

PESTICIDE USER SAFETY REQUIREMENTS:

- Discard clothing and other absorbent materials that have been heavily contaminated with this product. Do not reuse them.
- Follow manufacturers' instructions for cleaning and maintaining personal protective equipment (PPE). If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove personal protective equipment immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly.

ENVIRONMENTAL HAZARDS:

This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.



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DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. BETHOGUARD is to be incorporated into the following materials at suitable stages of the manufacturing process to preserve the integrity of the manufactured/treated materials. **Not for use in food grade paper, paperboard, paper coatings and adhesives.**
Not for use in textiles used for clothing articles.

TYPES OF MATERIALS:

Plastics (including films, foams, laminates, molded parts, pellets, sheets) such as Polyethylene, polypropylene, polyester; polyvinyl alcohol, epoxy resin, phenolic resin, polycarbonate, acetate, polystyrene, polyurethane, acrylic, etc.

Textiles & Fibers/Fabrics (including multi-fiber blends and synthetic blends with natural fibers) such as: acetate, acrylic, cotton, nylon, polyester, polyethylene, polypropylene, polyvinylchloride, rayon, wool, and coating/finishes applied to such materials

Building Materials including adhesives, caulks, grouts, gel coats, glazing compounds, sealants, patching compounds, dry wall, gypsum, perlite, plaster-like or mineral based materials, paper & paperboard (non-food contact),

APPLICATIONS

Manufactured materials may be used in the following end-use applications such that the finished product contains 0.10% to 1.0% by weight of the active ingredient:

Plastics, thermoset and thermoplastic resins: Carpet backings, foam underlay for carpets, synthetic non-leather materials, foam stuffing for cushions and mattresses, wire and cable insulation, wall coverings, covers or ticking, gaskets, weather stripping, boat covers, tents, tarpaulins, awnings, refuse containers, bath mats/appliqués, sponge or fiber mops, toilet brush receptacles, soap dish holders, boating & marine equipment, bags (blanket, garbage, garment, vacuum), curtains (window, shower, cubicle), liners (garbage, trays), humidifier components, appliance housings, automotive interiors, brooms, bristles & handles of brushes (**non-medical**), combs, buckets, carts.

Textiles & Fibers/Fabric: Tents, tarpaulins, awnings, shower curtains, curtains (window, shower, cubicle).

Building Materials (non-food contact): including adhesives, caulks (including tub & tile), grouts, gel coats, sealants, patching compounds, dry wall, gypsum, perlite, plaster-like or mineral based materials, paper & paperboard for insulation wallboard, and wall coverings, bathtubs and bathtub enclosures, flooring (concrete, epoxy, component fibers, vinyl, linoleum & coatings), handles & knobs, whirlpools, shower stalls, tile, ceiling tile, walls, wall coverings, partitions, toilets and toilet components/accessories.

Specific manufacturing directions for a given application will be provided by consultation with Janssen PMP.

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STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Store in a cool, dry place in original container. Do not use or store near heat or open flames. Protect product from direct sunlight.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinse water is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

Nonrefillable container: Do not reuse or refill this container. Offer for recycling, if available. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment, and then dispose of liner in a sanitary landfill or by incineration if allowed by State and Local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

Clean up spills immediately. Cover the pesticide powder with absorbent material, such as dry sand, sawdust or earth. Collect spill by sweeping or shoveling into an appropriate waste disposal container. Dispose of waste in a manner approved by Local authorities. Avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

NOTICE OF WARRANTY

Janssen PMP, a Division of Janssen Pharmaceutica NV warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with the directions under normal use conditions. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Janssen PMP. To the extent permitted by law, Janssen PMP disclaims any liability for consequential, special or indirect damages resulting from the use, handling, application, storage or disposal of this product or for damages in the nature of penalties, and the buyer and user waive any right that they may have to such damages. To the extent consistent with applicable law, Janssen PMP makes no warranties of merchantability or of fitness for a particular purpose or any other express or implied warranty except as stated above.

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