

43813-43

8/24/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

AUG 24 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

William R. Goodwine, Sr. Director
Regulatory Affairs & Product Development
Janssen PMP, a Division of Janssen Pharmaceutica, N.V.
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Subject: Notification per PR Notice 98-10
Wocosen® 450 EC
EPA Registration Number: 43813-43
Application Date: July 24, 2009
Receipt Date: July 28, 2009

Dear Mr. Goodwine:

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

Proposed Notification:

Label change as per PR Notice 2007-4.

Comment:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have further questions concerning this letter, please contact Killian Swift by telephone at 703-308-6346 or by email at swift.killian@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely yours

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

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



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<p>United States Environmental Protection Agency Washington, DC 20460</p>	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number _____
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Application for Pesticide - Section I

1. Company/Product Number 43813-43	2. EPA Product Manager Tracy Lantz	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) WOCOSN 450 EC	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:			
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	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>HDPE</u>
* 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		4. Size(s) Retail Container	5. Location of Label Directions
<input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		6.2, 50, 250 gallons (23.6, 189.4, 946.9 liters)	<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.		8. Date Application Received (Stamped)
2. Signature 	3. Title Senior Director, Regulatory Affairs & Product Development	
4. Typed Name William R. Goodwine	5. Date July 24, 2009	



July 24, 2009

Document Processing Desk (NOTIF)
Office of Pesticide programs (7504P)
U.S. Environmental Protection Agency
Antimicrobials Division
One Potomac Yard, Room S-4900
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Notifications per PR Notice 2007-4

- SAFETRAY® P (43813-15)
- WOCOSEN® 50 TK (43813-21)
- WOCOSEN 45 TK (43813-44)
- WOCOSEN 450 EC (43813-43)

Attn: Ms. Tracy Lantz
Acting Product Manager 34
Regulatory Management Branch II

Enclosed are completed Application for Pesticide Forms (including the certification statement in Section II), for the subject products, notifying the Agency of changes to the label container statement per Pesticide Registration (PR) Notice 2007-4.

These notifications are being resubmitted per the recommendation provided in the letter dated July 15, 2009 from N. Fitz, EPA, Field & External Affairs Division to H. Shah, ACC Biocides Panel (copy enclosed). Janssen PMP considers the container language of PR Notice 2007-4 appropriate for the subject products, which are manufacturing or end-use products for wood and material preservative use. These products do not contain any public health claims.

Please contact me if any questions regarding these notifications.

Sincerely,

William R. Goodwine
Senior Director
Regulatory Affairs & Product Development
T: 609-730-2607 F: 609-730-2202
bgoodwi@its.jni.com

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WOCOSEN® 450 EC

Fungicide for Material & Wood Preservation

ACTIVE INGREDIENT: (w/w)	
PROPICONAZOLE	34.0%
IPBC: 3-iodo-2-propynyl butyl carbamate	16.0%
INERT INGREDIENTS: (w/w)	
	50.0%
TOTAL	100.0%

NOTIFICATION 8/24/09
 Date Reviewed:
 Reviewed By: *[Signature]*

Product weight: 9.3 lbs/gallon. Contains 2.8 lbs Propiconazole and 1.3 lbs IPBC per gallon.

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID	
IF SWALLOWED	<ul style="list-style-type: none"> • Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told by a Poison Control Center or doctor. • Do not give anything by mouth to an unconscious person.
IF INHALED	<ul style="list-style-type: none"> • 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 for further treatment advice.
IF IN EYES	<ul style="list-style-type: none"> • 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. • Call a Poison Control Center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a Poison Control Center or doctor for treatment advice
HOT LINE NUMBER	
<p>For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents) call the National Pesticide Telecommunications Network at 1-800-858-7378. For chemical emergency assistance (spill, leak, fire, or accident), call Chem-Trec at 1-800-424-9300.</p>	
<p>Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment.</p>	
<p>NOTE TO PHYSICIAN: "Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

NET CONTENTS: 50 gallons (189.4 liters)

EPA REG. NO. 43813-43

EPA EST. NO.

JANSSEN PMP

a Division of Janssen Pharmaceutica NV
 1125 Trenton-Harbourton Rd.
 Titusville, NJ 08560-0200

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

Causes skin irritation and moderate eye irritation. Harmful if swallowed, absorbed through the skin, or inhaled. Do not get in eyes or on clothing. Avoid breathing spray mist. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT

Applicators and other handlers must wear: Long sleeved shirt and long pants, socks and shoes, chemical-resistant gloves (such as: Barrier Laminate, or any of the following gloves at ≥ 14 mils thickness: butyl nitrile, neoprene rubber, polyvinyl chloride or Viton), goggles or face shield.

USER SAFETY REQUIREMENTS AND RECOMMENDATIONS

Follow the manufacturer's instructions for cleaning/maintaining personal protective equipment (PPE). If no such instructions exist for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry.

USER SAFETY RECOMMENDATIONS

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

ENVIRONMENTAL HAZARDS

For terrestrial uses: Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate. Apply this product only as specified on the label.

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.

DIRECTIONS FOR USE:

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

STORAGE AND DISPOSAL:

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

PESTICIDE STORAGE: Store in a cool, dry place.

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 HANDLING:

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows:

[For containers ≤ 5 gallons in size] - Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[For containers > 5 gallons in size] - Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

PHYSICAL OR CHEMICAL HAZARDS: Do not use, pour, spill or store near heat or open flame.

SAPSTAIN AND MOLD CONTROL:

WOCOSEN 450 EC is used to control sapstain and mold in freshly cut hardwood and softwood lumber, poles, posts, timbers and other manufactured wood products. Examples of other wood products include: Logs: Fungal staining can be inhibited in freshly debarked logs used for log home construction, export, yarding prior to sawing and other purposes.

Wood Furnish: Engineered wood composites, such as particle board, wafer board, oriented strand board, and similar products can be protected from fungal discoloration during storage by treatment with WOCOSEN 450 EC.

Wood Chips/Saw Dust: Treatment of wood chips, saw dust or other similar by products intended for papermaking (Not for food grade/food contact paper or paper board) reduces fungal discoloration and lowers bleaching requirements for finished paper products.

Plywood Veneer: Treatment with WOCOSEN 450 EC is effective for freshly peeled green veneer and other similar plywood furnish that can be especially subject to sapstain and mold development that can interfere with appearance or laminating adhesive performance.

WOCOSEN 450 EC is applied by dipping or spraying the wood until complete surface wetting is achieved. For **bulk dip tanks** WOCOSEN 450 EC treating solution is prepared by diluting 0.1 gallons (12.8 oz.) to 0.75 gallons WOCOSEN 450 EC in 100 gallons of water. Agitate vigorously until completely dispersed. For **conventional spray systems** a 0.2% to 1.5% WOCOSEN 450 EC spray solution is used. The treating solution is prepared by mixing 0.2 to 1.5 gallons of WOCOSEN 450 EC in 100 gallons of water. In **electrostatic spray** applications, WOCOSEN 450 EC dilution is not required, treatment strength is varied by number of application nozzles used and line speed. Rates, for all applications used, will vary according to temperature, humidity, wood moisture, storage conditions, etc. Contact your local WOCOSEN 450 EC product representative for application advice.

Remove sawdust and other debris from treating solution on a regular basis to maintain correct concentration of WOCOSEN 450 EC in application solution. To prevent fungal attack below the surface of the wood, freshly sawn lumber should be treated within 24 hours. Treated lumber should be protected from rain and removed from direct soil/ground contact.

DECAY AND STAIN PROTECTION

Description: WOCOSEN 450 EC is a wood preservative concentrate that requires dilution with water prior to use on wood products to protect against decay (brown and white rot) and staining fungi (blue stain).

Product Uses: For application to millwork, shingles & shakes, siding, plywood, and structural lumber & composites that are used in above ground applications only. Do not use on wood which will come in contact with food.

Wood Preparation: Machine, cut, glue, and sand wood as desired before treating. Do not use over previously finished or stained wood without stripping off old finish. Wood must be clean and dry before treatment. Wood for pressure treatment should be kiln dried or air seasoned to a moisture content, of about 25% or less, that will permit adequate penetration of preservative during treatment.

Treatment: Apply by immersion, roller coater, flood, spray, brush or pressure treatment processes (double vacuum, full-cell or modified full-cell). For non-pressure application methods, mix 1.5 to 3 gallons of WOCOSEN 450 EC in 100 gallons of water. Wood products to be treated by the bundle-dipping process should be completely immersed for three (3) minutes. Individual wood pieces treated by immersion, roller-coater or flood shall be treated for not less than fifteen (15) seconds. Coverage for brush and spray application is approximately 150 square feet per gallon of treating solution, but varies by the species and condition of the wood. Pressure treatment should be performed according to the methods described in the American Wood Preservers' Association (AWPA) Standards. A retention level of 0.0375 pounds total active ingredient per cubic foot (pcf) is recommended. All treated wood must be held on the drip pad until drippage has stopped. Any surface, cut after first treatment should be retreated using 1.5% a.i. concentration solution.

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Finishing: Before glazing, staining, painting, varnishing, or application of water repellents, treated wood should be completely dry and odor-free. For non-pressure applications, allow 4-8 hours drying time under average temperature and humidity conditions; treated wood can be heat dried for plant production. Pressure treated wood requires drying after treatment to a moisture content suitable for the type of coating to be applied.

Clean-up: Use water to remove wet WOCOSEN 450 EC wood preservative from all surfaces, brushes and rollers.

COATINGS, CAULKS, SEALANTS, ADHESIVES, AND INKS:

Not for use in coatings and adhesives which will come in contact with paper or paperboard.

Sufficient mixing to ensure adequate dispersion of the biocide is required. WOCOSEN 450 EC should be used at levels between 0.15 and 3.75% based on the total weight of the formulation to inhibit fungal disfigurement and deterioration.

METALWORKING FLUIDS:

Use WOCOSEN 450 EC to inhibit fungal degradation of water based and water emulsifiable cutting fluids and coolants used in metalworking operations. Add WOCOSEN 450 EC to the fluid concentrate or to the diluted metalworking fluid in an amount that will provide 50 to 1,000 ppm active ingredient in the diluted fluid.

TEXTILES

For the control of odor and stain causing microorganisms in textiles of the following products: shower curtains, carpet backing, awnings, boat covers, canvas, cordage, tents, tarpaulins, and wall coverings.

Addition of up to 3,000 ppm total active ingredient (0.3% of WOCOSEN 450 EC), based on weight of goods, can inhibit the growth of mold and mildew that cause stains, odors and product degradation in textiles, fabrics and fibers composed of acetate, acrylic, acrylonitrile butadiene styrene, natural fibers (cotton, paper, wool, etc.), nitrile copolymers, nylon, polyester, polyethylene, polypropylene, rayon, rubber (natural & synthetic), coatings/finishes composed of silicone, urethane or vinyl applied to such materials. The material should be added at an appropriate manufacturing step to ensure adequate mixing and complete, uniform coverage of the treated material. Product can be applied by dye incorporation, pad, exhaust, or spray application.

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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Propiconazole is manufactured by Syngenta, Basel, Switzerland

PMP 05/09