

43813-21

8/24/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

AUG 24 2009

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® 50 TK
EPA Registration Number: 43813-21
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 cursive script that reads "ShaRon Carlisle".

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



Please read instructions on reverse before completing form.

2096

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
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Application for Pesticide - Section I

1. Company/Product Number 43813-21	2. EPA Product Manager Tracy Lantz	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) WOCOSEN 50 TK	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	Other (Specify) <u>HDPE</u>
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
* 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 52 & 261 GALLONS (198 & 991 LITERS)		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 July 24, 2009			



JANSSEN PMP

PRESERVATION AND MATERIAL PROTECTION
a division of Janssen Pharmaceutica NV

3046

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
wgoodwi@its.inj.com

4096

WOCOSEN™ 50TK

Manufacturing Concentrate

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

For use in formulating industrial preservative products

ACTIVE INGREDIENT: (w/w)

PROPICONAZOLE:

1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]

-1H-1,2,4-triazole

50.0%

INERT INGREDIENTS: (w/w)

50.0%

TOTAL

100.0%

Contains 4.17 lbs. active ingredient/gallon

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If swallowed	-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 to do so by a poison control center or doctor. -Do not give anything by mouth to an unconscious person.
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 for treatment advice.
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 for treatment advice.
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 for further treatment advice.
HOT LINE NUMBER:	
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.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
There is no specific antidote for WOCOSEN 50TK. Give a saline laxative and supportive therapy.	

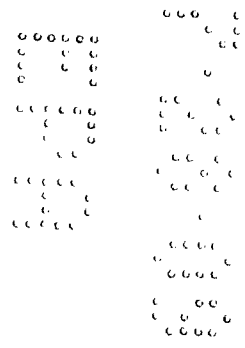
NET CONTENTS: 261 gallons (991 liters)

EPA REG. NO. 43813-21

EPA EST. NO. 43813-BL-2

JANSSEN PMP

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



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

CAUTION

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

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 permit 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 local State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in original container in a cool, dry place.

PESTICIDE DISPOSAL:

Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate 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.

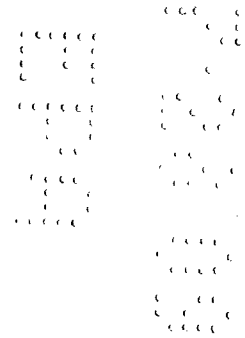
CONTAINER HANDLING:

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

Empty the remaining contents into application equipment or a mix tank. Fill the container 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.

TMTrademark of Janssen Pharmaceutica.
*Propiconazole is manufactured by Syngenta, Basel, Switzerland



leaf

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

Description: This product may be used to formulate products for specific uses not listed on the manufacturing use product label, if the formulator or user group has complied with U.S. EPA data submission requirements regarding the support of such uses. Each formulator is responsible for obtaining EPA registration for his end use product(s).

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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