

43813-15

08-17-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

AUG 17 2009

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

William R. Goodwine  
Senior Director  
Regulatory Affairs & Product Development  
Janssen PMP  
1125 Trenton-Harburton Road  
Titusville, NJ 08560-0200

Subject: Notification in Accordance with PR Notice 98-10  
Safetray P  
EPA Registration No. 43813-15  
Application Date: July 24, 2009  
Receipt Date: July 28, 2009

Dear Mr. Goodwine:

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

**Proposed Notification**

Label change due to PR Notice 2007-4

**General Comments**

Based on a review of the material submitted, the following comments apply:

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

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6427 or email address at [Carlisle.shaRon@epa.gov](mailto:Carlisle.shaRon@epa.gov) or Renae Whitaker by telephone at (703) 308-7003 or email at [whitaker.renae@epa.gov](mailto:whitaker.renae@epa.gov) during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in cursive script that reads "ShaRon Carlisle".

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



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 <b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:30px; text-align: center;"><input type="checkbox"/></td> <td style="padding-left: 5px;">Registration</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="padding-left: 5px;">Amendment</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="padding-left: 5px;">Other</td> </tr> </table>	<input type="checkbox"/>	Registration	<input type="checkbox"/>	Amendment	<input checked="" type="checkbox"/>	Other	OPP Identifier Number  
<input type="checkbox"/>	Registration							
<input type="checkbox"/>	Amendment							
<input checked="" type="checkbox"/>	Other							

**Application for Pesticide - Section I**

<b>1. Company/Product Number</b> 43813-15	<b>2. EPA Product Manager</b> Tracy Lantz	<b>3. Proposed Classification</b> <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
<b>4. Company/Product (Name)</b> SAFETRAY P	<b>PM#</b> 34	
<b>5. Name and Address of Applicant (Include ZIP Code)</b> 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	<b>6. Expedited Review.</b> 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"/> Resubmission in response to Agency letter dated _____  <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application.  <input type="checkbox"/> Other - Explain below.
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**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**

<b>1. Material This Product Will Be Packaged In:</b>					
<b>Child-Resistant Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Unit Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Water Soluble Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>2. Type of Container</b> <input type="checkbox"/> Metal <input checked="" 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		
<b>3. Location of Net Contents Information</b> <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		<b>4. Size(s) Retail Container</b> 2.6 GALLONS (10 LITERS)		<b>5. Location of Label Directions</b> <input type="checkbox"/> On Label	
<b>6. Manner in Which Label is Affixed to Product</b> <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled			<input type="checkbox"/> Other _____		

**Section - IV**

<b>1. Contact Point</b> (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
<b>Name</b> William R. Goodwine	<b>Title</b> Senior Director, Regulatory Affairs & Product Development	<b>Telephone No. (Include Area Code)</b> (609) 730-2607
<b>Certification</b> 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.		<b>8. Date Application Received</b> (Stamped)
<b>2. Signature</b> 	<b>3. Title</b> Senior Director, Regulatory Affairs & Product Development	
<b>4. Typed Name</b> William R. Goodwine	<b>5. Date</b> July 24, 2009	

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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.

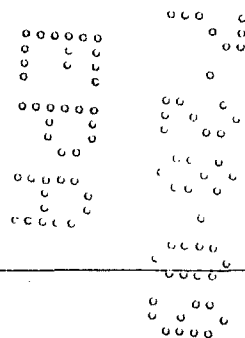
These notifications are being resubmitted per the recommendation provided in the letter dated July 15, 2009 from N. Fitz, EPA, Field & External Affairs Division to H. Shah, ACC Biocides Panel (copy enclosed). Janssen PMP considers the container language of PR Notice 2007-4 appropriate for the subject 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.inj.com](mailto:bgoodwi@its.inj.com)



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**NOTIFICATION**  
Date Revised: *5/11/09*  
Reviewed By: *R. H. ...*

# SAFETRAY® P

Wood Preservative for the Mushroom Industry

For the prevention of wood rot and decay and for the control of adhesion and penetration of mushroom mycelium in timber trays and benches allowing for an easy tip out of the compost

**ACTIVE INGREDIENT: (w/w)**

**PROPICONAZOLE\*:**

1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole 23.6%

**INERT INGREDIENTS: (w/w)** 76.4%

**TOTAL** 100.0%

Contains 2.05 lbs. active ingredient/gallon

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

FIRST AID	
<b>If swallowed</b>	-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.
<b>If in eyes</b>	-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
<b>If on skin or clothing</b>	-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.
<b>If inhaled</b>	-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.
<b>HOT LINE NUMBER:</b>	
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	
<b>NOTE TO PHYSICIAN</b>	
There is no specific antidote for Safetray P. Give a saline laxative and supportive therapy.	

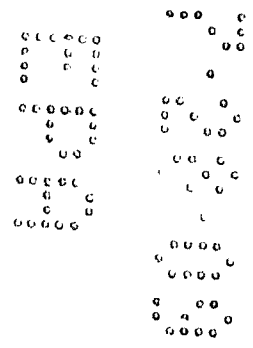
NET CONTENTS: 2.6 gallons (10 liters)

EPA REG. NO. 43813-15

EPA EST. NO. 074263-DEU-001

Manufactured for:

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



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

**CAUTION**

Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing spray mist. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS**

Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters. 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 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**

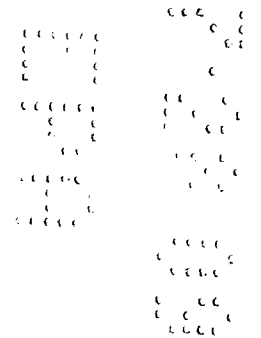
Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative 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 and drain for 10 seconds after the flow begins to drip. Fill the container 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.

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.



## DIRECTIONS FOR USE

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

To prevent wood rot and decay and to control adhesion and penetration of mushroom mycelium in timber trays and benches add 19.5 fl. oz. of SAFETRAY™ P to 25 gal. of water to achieve a treating concentration of 1,500 ppm active ingredient.

## MIXING

Half-fill the spray or dip tank with water. Add the appropriate amount of SAFETRAY™ P. Triple rinse empty container and add the rinsate to the tank. Stir gently and add water up to the required volume. A few drops of an anti-foam agent may be added to avoid excessive foaming.

## APPLICATION

### SPRAY

Between each crop of mushrooms, apply the treating solution with a large droplet sprayer on the internal surface of the trays or to the inside surface of the side, end and bottom boards of the benches. To insure complete wetting of the wood surface spray approximately 25 gallons of treating solution per 5,000 sq. ft. of wood surface. Make sure all corners are well treated. Let the trays or bench boards dry before adding compost. The trays should be allowed to dry in a sheltered, well-ventilated place.

### DIP

Submerge trays or boards in treating solution for not more than 30 seconds, then remove and allow to drain back into dip tank. Let the trays or boards dry in a sheltered, well-ventilated place before adding compost.

### 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. Crop injury, 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 or handling of this product. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, JANSSEN PMP MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

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\*Propiconazole is manufactured by Syngenta, Basel, Switzerland

Rev. 05/09

