

43813-32

6/18/2005

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration	OPP Identifier Number
		<input type="checkbox"/> Amendment	
		<input checked="" type="checkbox"/> Other	

**Application for Pesticide - Section I**

1. Company/Product Number Janssen Pharmaceutica/43813-32	2. EPA Product Manager Mary Waller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Janssen Pharmaceutica/PENBOTEC 400 SC	PM# 21	
5. Name and Address of Applicant (Include ZIP Code) Janssen Pharmaceutica 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 _____	<b>NOTIFICATION</b>  JUL 18 2005
<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.)**

Label Change: Include additional disease claim for pome fruit - Phaciidiopycnis rot caused by P. piri. "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of 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 this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, 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 type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input 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				
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions			
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph Paper glued <input type="checkbox"/> 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 Sr. Director	Telephone No. (Include Area Code) (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.		6. Date Application Received  <b>(Stamped)</b>
2. Signature <i>William R. Goodwine</i>	3. Title Sr. Director	
4. Typed Name William R. Goodwine	5. Date JUNE 24, 2005	

# PENBOTEC® 400 SC

For postharvest use on pome fruits

**Active Ingredient:**

Pyrimethanil: 4,6-dimethyl-N-phenyl-2-pyrimidinamine\*

37.14%

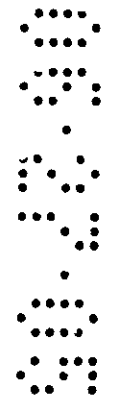
**Other Ingredients:**

62.86%

**Total:**

100.00%

Contains 3.27 lbs. active ingredient per gallon (400 g/L)



**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

<b>FIRST AID</b>	
<b>If on skin</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>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>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.	

NET CONTENTS: 33.8 fl. oz. (1 liter)

EPA REG. NO. 43813-32

EPA EST. NOs.: 074263-DEU-001; 43813-BL-001; 43813-002

**JANSSEN PHARMACEUTICA Inc.**

1125 Trenton-Harbourton Road

Titusville, NJ 08560-0200

**NOTIFICATION**

JUL 18 2005

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

**CAUTION**

Harmful if swallowed, inhaled or absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves (such as Natural Rubber, Selection Category A). Remove and wash contaminated clothing before reuse. Avoid breathing spray mist.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

**ENVIRONMENTAL HAZARDS**

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment, or disposal of wastes. Apply this product only as specified on this 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**

**PESTICIDE STORAGE:** Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**GENERAL INFORMATION:**

PENBOTEC 400 SC fungicide controls blue and gray mold and *Phacidiopycnis rot (P. piri)* on pome fruit. Use of PENBOTEC 400 SC should be integrated into an overall disease management program within each packinghouse.

## FUNGICIDE RESISTANCE MANAGEMENT

### GROUP 9 FUNGICIDE

PENBOTEC 400 SC is an anilinopyrimidine fungicide that does not exhibit cross-resistance to sterol-inhibiting or benzimidazole fungicides. PENBOTEC 400 SC interferes with the secretion of enzymes necessary for infection by several postharvest pathogens, therefore, preventative applications soon after harvest or injury is necessary for optimal product performance. Fungal pathogens can develop resistance to products with the same mode of action when used repeatedly. Because resistance development cannot be predicted, use of postharvest resistance management strategies should be practiced. These may include rotating and/or tank mixing with products having different modes of action. Responsible resistance management practices are necessary to ensure the long-term effectiveness for decay control.

#### MIXING INSTRUCTIONS

Fill tank with half of the required amount of water or water wax and start mechanical agitation. Add the required amount of PENBOTEC 400 SC and then add the remaining volume of water or water wax. Maintain agitation after mixing and do not allow treating solution to stand overnight or for prolonged periods. For in-line injection systems better distribution will be achieved by injecting a larger volume of a more dilute solution per unit of time.

The physical compatibility of PENBOTEC 400 SC with all tank mix partners and wax types has not been fully investigated. This product cannot be mixed with any product containing a label prohibition against such mixing. No label dosage rates for the individual products may be exceeded. Prior to tank mixing with PENBOTEC 400 SC, conduct a jar test with the volumes and rates typically used for postharvest disease control. Add proportionate amounts of the products to a small container of water or water wax in the following order: Wettable powders and water-dispersible granules first, followed by liquid flowables, and emulsifiable concentrates last. After thorough mixing, let stand for at least 15 minutes. Separation, globules, sludge, flakes or other precipitates are indicative of physical incompatibility. Physical compatibility is indicated if the combination remains mixed or can be remixed readily. **THE CROP SAFETY OF ALL POTENTIAL PESTICIDE TANK MIXES WITH PENBOTEC 400 SC INCLUDING ANTI-SCALD AGENTS AND WAXES, HAS NOT BEEN TESTED ON ALL CROPS AND VARIETIES. BEFORE APPLYING ANY TANK MIXTURE, SAFETY TO THE TARGET CROP SHOULD BE CONFIRMED.**

#### USE RATES:

<b>POME FRUITS</b>			
<b>Treatment Method</b>	<b>Rate Fl.oz/100 gal</b>	<b>Treatment Time (min)</b>	<b>Concentration A.I. (ppm)</b>
Dip, wash tanks	16 - 32	1	500-1000
Drenchers	16 - 32	1	500-1000
Aqueous line spray	32	1	1000
Wax line spray	64	1	2000

Periodically measure the PENBOTEC 400 SC concentration of the treating solutions from drenchers, dips and wash tanks to maintain the proper level of active ingredient. Aqueous applications must be applied prior to fruit receiving any wax applications.

**Treatment Schemes**

Double treatment with PENBOTEC 400 SC is the maximum allowed on pome fruits. Acceptable multiple treatment scenarios are presented below:

Treatment Scenario	PENBOTEC 400 SC Application Methods				
	Drench	Dip & Wash tanks	Aqueous spray	Storage Wax	Shipping Wax
<b>POME FRUIT</b>					
1	√	√			
2	√		√		
3	√				√
4		√			√
5			√		√
6		√	√		

**NOTICE OF WARRANTY**

Janssen Pharmaceutica 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 other than as specified on the label, all of which are beyond the control of Janssen Pharmaceutica. In no case shall Janssen Pharmaceutica be liable for consequential, special or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the Buyer. JANSSEN PHARMACEUTICA MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OF IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

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\* Pyrimethanil manufactured by Bayer CropScience AG

Rev. 05/05

JANSSEN



PHARMACEUTICA INC.

6/6

June 23, 2005

Document Processing Desk (NOTIF)  
U.S. Environmental Protection Agency  
Office of Pesticide Programs (7504C)  
Room 266A Crystal Mall 2  
1801 South Bell Street  
Arlington, VA 22202-4501

Attn: Ms. Mary Waller  
Product Manager (PM 21)

SUBJECT: PENBOTEC™ 400 SC; EPA Registration No. 43813-32  
Notification: Addition of disease control claim

Dear Ms. Waller:

Attached is notification that Janssen is adding the claim for control of Phacidiopycnis rot, (causal organism *P. pini*) on pome fruit to the PENBOTEC 400 SC label, effective with the next printing of final labeling. Five copies of the specimen labels are attached, showing the additional label claim highlighted in yellow.

This change has been discussed and accepted by Ms. Shereda Hobgood as meeting the requirements for notification.

Sincerely,

Bill Goodwine  
Sr. Director  
Plant & Material Protection Division  
609/730-2607 - PH  
609/730-3138 - FAX  
bgoodwi@janus.jnj.com

cc: S. Hobgood

1125 TRENTON-HARBOURTON ROAD  
POST OFFICE BOX 200  
TITUSVILLE, NEW JERSEY 08560-0200  
(609) 730-2000

us.janssen.com

