



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mrs. Joanne Haman-Hoy
Associate Regulatory Affairs
Janssen PMP a Division of Janssen Pharmaceutica, N.V.
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

MAY 30 2008

RE: Notification for Addition of disease claim
EPA Reg. No.: 43813-32
Date of Submission: April 24, 2008

Dear Mrs. Haman-Hoy:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated April 24, 2008, for the product, Penbotec 400 SC. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or
Joyce Edwards of my staff at 703-308-5479.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



<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 Janssen PMP/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 PMP/PENBOTEC 400 SC	PM# 21	
5. Name and Address of Applicant (Include ZIP Code) Janssen PMP, a Division of Janssen Pharmaceutica NV 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)(ii), 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.)

Label Change: Include additional disease claim for pome fruit - bull's eye rot [Neofabraea perennens & N. malicorticis]. "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		If "Yes" Package wgt No. per container			
3. Location of Net Contents Information		4. Size(s) Retail Container		5. Location of Label Directions	
<input type="checkbox"/> Label <input type="checkbox"/> Container				<input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product				<input type="checkbox"/> Lithograph <input type="checkbox"/> 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 Joanne Haman-Hoy	Title Associate Regulatory Affairs	Telephone No. (Include Area Code) (609) 730-2609
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 	3. Title Associate Regulatory Affairs	
4. Typed Name Joanne Haman-Hoy	5. Date April 24, 2008	

PENBOTEC® 400 SC

For postharvest use on citrus and pome fruits

<i>Active Ingredient:</i>	
Pyrimethanil: 4,6-dimethyl-N-phenyl-2-pyrimidinamine*	37.14%
<u>Other Ingredients:</u>	<u>62.86%</u>
<i>Total:</i>	100.00%

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

KEEP OUT OF REACH OF CHILDREN

CAUTION

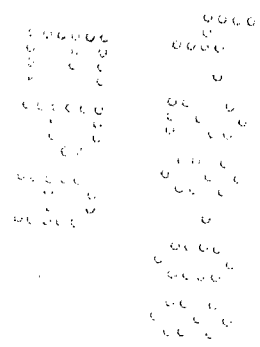
FIRST AID	
If on skin	-Take off contaminated clothing. -Rinse skin immediately with plenty of water for 15-20 minutes. -Call a poison control center or doctor for treatment advice.
If inhaled	-Move person to fresh air. -If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. -Call a poison control center or doctor for further treatment advice
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.
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.	

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

EPA REG. NO. 43813-32
EPA EST. No.: 074263-DEU-001



1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200



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:

[REDACTED] bull's eye rot (*Neofabraea perennans* & *N. malicorticis*) [REDACTED] when applied in aqueous treating systems or when applied in diluted storage wax. In citrus pack waxes, PENBOTEC 400 SC provides suppression of green and blue mold. 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:

CITRUS FRUITS			
Treatment Method	Rate Fl.oz/100 gal	Treatment Time (min)	Concentration A.I. (ppm)
Dip, wash tanks	32	2	1000
Drenchers	16	2-4	500
Aqueous line spray	64	1	2000
Wax line spray: Storage & Pack Wax	64	1	2000

POME FRUITS			
Treatment Method	Rate Fl.oz/100 gal	Treatment Time (min)	Concentration A.I. (ppm)
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. Citrus fruits treated by aqueous or wax line spray applications should be cleaned prior to application. Aqueous applications must be applied prior to fruit receiving any wax applications. Citrus storage wax should be pre-diluted to the recommended use rate of the wax prior to addition of the PENBOTEC 400 SC fungicide.

Treatment Schemes

PENBOTEC 400 SC may be applied to citrus fruits by a maximum combination of three application methods. Double treatment 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
CITRUS					
1	√			√	
2	√			√	√
3	√	√		√	
4				√	√
5		√		√	
6	√				√
7		√			√
8	√	√			
9	√	√			√
10			√		√
11	√		√		
12	√		√		√
POME FRUIT					
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.

® Registered trademark of Janssen Pharmaceutica N.V.

* Pyrimethanil manufactured by Bayer CropScience AG

Rev. 04/08



JANSSEN PMP

PRESERVATION AND MATERIAL PROTECTION
a division of Janssen Pharmaceutica NV

8/8

April 24, 2008

Document Processing Desk (NOTIF)
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504C)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
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 PMP, a Division of Janssen Pharmaceutica NV is adding an additional disease claim for bull's eye rot [*Neofabraea perennans* & *N. malicorticis*] on pome fruit to the PENBOTEC 400 SC label. Five copies of the specimen labels are attached, showing the additional label claim highlighted in yellow.

Sincerely,

Joanne Haman-Hoy
Associate Regulatory Affairs
Janssen PMP, a Division of Janssen Pharmaceutica NV

609/730-2609 - PH
609/730-3138 - FAX
jhoy1@janus.jnj.com - E-MAIL