

43813-32

8/13/2004

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg.
Number:

43813-32

Date of Issuance:

AUG 13 2004

Term of Issuance:

Conditional

Name of Pesticide Product:

PENBOTEC 400 SC

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Janssen Pharmaceutica Inc.
1125 Trenton-Harbourton Road
P.O. Box 200
Titusville, NJ 08560-0200

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Sec. 3(c)(7)(C) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Make the following labeling change before the product is released for shipment: Revise the EPA Registration Number to read, "EPA Registration Number 43813-32".
3. For the next five years from the date of this registration and as additionally required, provide an annual report on the market penetration and market share of pyrimethanil for each of the registered crops.
4. Submit one copy of the final printed label before the product is released for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Mary L. Waller

Mary L. Waller, Product Manager (21)
Fungicide Branch, Registration Division

Date:

8/13/04

PENBOTEC™ 400 SC

For postharvest use on citrus and 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

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.
<p align="center">HOT LINE NUMBER:</p> <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>	
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

ACCEPTED
with COMMENTS
In EPA Letter Dated:

8/13/04

JANSSEN PHARMACEUTICA Inc.
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.

43813-32

**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 on pome fruit. On citrus, PENBOTEC 400 SC provides control of blue and green mold 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.

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