



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:

43813-38

Date of Issuance:

NOV 5 2004

Terms of Issuance:
Conditional

Name of Pesticide Product:

PHILABUSTER™ 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
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, this product is conditionally registered under the Federal Insecticide, Fungicide and Rodenticide Act as amended. 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 Section 3(c)(7)(A) provided that you comply with the conditions of registration specified on page 2. 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

Signature of Approving Official:

Mary J. Waller

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

Date:

11/5/04

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Conditions of Registration:

**EPA Reg. No. 43813-38
PHILABUSTER™ 400 SC**

1. Submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) 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 changes to the label that you submitted November 4, 2004 before you release the product for shipment:
 - A. Revise the EPA Registration Number to read "EPA Reg. No. 43813-38"
 - B. Put the section "User Safety Recommendations" in a box to set this section off from the rest of the text.
 - C. Move the header "Directions for Use" and the following sentence to immediately before the header "FUNGICIDE RESISTANCE MANAGEMENT:"
 - D. In the section "Storage and Disposal", change the subheader "Storage" to "Pesticide Storage"
 - E. In the section "Storage and Disposal", change "CONTAINER DISPOSAL" to "CONTAINER DISPOSAL - PLASTIC CONTAINERS"
 - F. Your "Application for Pesticide Registration" dated January 26, 2004 indicates that metal containers may be used for this product. Labels used with metal pesticide containers must contain the following container disposal instructions:
"CONTAINER DISPOSAL - METAL CONTAINERS: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities."
3. Submit one copy of the revised final printed label before releasing the product for shipment.
4. Submit acceptable Storage Stability (830.6317) and Corrosion Characteristics (830.6320) data within 15 months from the date of this Registration.

A copy of the label that you submitted November 4, 2004 stamped "Accepted with Comments" is enclosed for your records.

The revised Basic Confidential Statement of Formula (CSF) dated August 20, 2004 is acceptable and will be added to the Agency's files for this product. A copy of the Agency's Product Chemistry Review dated August 18, 2004 which summarizes the review of the product chemistry data and the revised CSF is enclosed for your records.

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PHILABUSTER™ 400 SC

For postharvest use on citrus fruits

Active Ingredient:

Pyrimethanil: 4,6-dimethyl-N-phenyl-2-pyrimidinamine*.....17.21%

Imazalil sulfate: ±1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-1H-

imidazole sulfate..... 22.95%

Other Ingredients:..... 59.84%

Total: 100.00%

Contains 1.7 and 2.2 lbs. pyrimethanil and imazalil sulfate, respectively per gallon.

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this pesticide is registered under EPA Reg. No. 43813-38

NOV 5 2004
EPA Letter Dated: 11/5/04
ACQUITTED WITH COMMENTS

FIRST AID	
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. -Call a poison control center or doctor for 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.
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
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 Probable mucosal damage may contraindicate the use of gastric lavage.	

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

Net weight - 9.7 lbs. per gallon.

EPA REG. NO. 43813-XX

EPA EST. NO. 074263-DEU-001

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

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

DANGER PELIGRO

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

HANDLER PERSONAL PROTECTIVE EQUIPMENT (PPE)

Wear protective eyewear (goggles, face shield, or safety glasses). Wear long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves (such as Natural Rubber, Selection Category A).

PESTICIDE USER SAFETY REQUIREMENTS

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. If pesticide gets inside clothing/PPE, remove immediately, wash thoroughly, and put on clean clothing. Wash the outside of gloves before removing.

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

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

STORAGE: Store in a cool dry place in the original container away from food and feed.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. 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 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.

FUNGICIDE RESISTANCE MANAGEMENT: GROUP 3 & 9 FUNGICIDES

PHILABUSTER combines the active ingredients imazalil sulfate and pyrimethanil, two fungicides with different modes of action, into a single product to facilitate adoption of resistance management strategies in postharvest disease control. Pyrimethanil is an anilinopyrimidine fungicide (Group 9) that interferes with the secretion of enzymes necessary for infection by several postharvest pathogens, while imazalil sulfate is an imidazole fungicide (Group 3) that inhibits sterol synthesis thus affecting cell wall permeability. Pyrimethanil does not exhibit cross-resistance to sterol-inhibiting or benzimidazole fungicides.

Because resistance development cannot be predicted, postharvest resistance management strategies and sanitation practices should be followed. Fungal pathogens can develop resistance to products with the same mode of action when used repeatedly. When fruit lots are treated with multiple fungicide applications for long-term storage and transport, rotate PHILABUSTER with products or tank mixes containing at least one active ingredient of a different fungicide Group (e.g. thiabendazole –Group 1 or sodium bicarbonate – Group M). Rotate fungicides when spore monitoring screening results indicates a high sensitivity of the green or blue mold pathogens in the existing spore population of the packinghouse. Continued use of PHILABUSTER under these circumstances can lead to reduced efficacy. Contact your local service company or Janssen Pharmaceutica Inc. for information on the FUNGAFLOR® Spore Monitoring Program. Responsible resistance management practices are necessary to ensure the long-term effectiveness of PHILABUSTER for postharvest citrus decay control.

MIXING INSTRUCTIONS

Fill tank with half of the required amount of water or pre-diluted storage (water) wax and start mechanical agitation. Slowly add the required amount of PHILABUSTER and then add the remaining volume of water or diluted storage wax. Slow addition of the PHILABUSTER to the water or pre-diluted storage wax is important to achieve a high level of suspension. Maintain agitation after mixing and during application. Begin application with the treating solution only after the PHILABUSTER has completely and uniformly dispersed into the mix carrier. 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 PHILABUSTER with all tank mix partners and storage waxes has not been fully investigated. Prior to tank mixing, 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 diluted storage 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. Once compatibility has been proven, use the same procedure for adding the required ingredients to the larger mix tank. **THE CROP SAFETY OF ALL POTENTIAL PESTICIDE TANK MIXES WITH PHILABUSTER INCLUDING STORAGE WAXES, HAS NOT BEEN TESTED ON ALL CROPS AND VARIETIES. BEFORE APPLYING ANY TANK MIXTURE, SAFETY TO THE TARGET CROP SHOULD BE CONFIRMED.**

If using PHILABUSTER in a tank mixture, observe all directions for use, crop/sites, use rates, dilution ratios, precautions, and limitations that appear on the tank mix product label. No label dosage rates should be exceeded, and the most restrictive label precautions and limitations should be followed. **Tank mixtures are permitted only in those states where the tank mix partner is registered.**

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CROP USE DIRECTIONS

Citrus Fruit Crop Group – includes the commodities Calamondin, Citrus citron, Grapefruit, Kumquat, Lemon, Lime, Mandarin, Orange (sweet & sour), Pummelo, and Satsuma mandarin.

Use PHILABUSTER fungicide for the control of the following postharvest diseases caused by *Penicillium italicum* (blue mold), *Penicillium digitatum* (green mold), *Colletotrichum gloeosporioides* (anthracnose) and *Phomopsis citri* & *Diaporthe citri* (stem-end rot) on citrus fruits. Use of PHILABUSTER should be integrated into an overall disease management program within each packinghouse. Provides curative and preventative activity - treat fruit within the same day of picking. For suppression of sporulation, use the highest labeled rate.

FOR USE IN DILUTED STORAGE WAX AND AQUEOUS APPLICATIONS ONLY. NOT FOR USE IN PACK OR FINISHING WAXES.

Dip and Wash Tank Application: Mix 16 - 48 fl. oz. of PHILABUSTER in 100 gallons of water. Treating time should not exceed 2 minutes.

Drench: Mix 16 - 48 fl. oz. of PHILABUSTER in 100 gallons of water. Drench cycle should not exceed 4 minutes.

Aqueous Line Spray Application: Mix 32 – 64 fl. oz. of PHILABUSTER in 100 gallons of water and apply to fruit over conveyer rollers or brushes using T-jet, control droplet applicator (CDA), flood/shower, drip or similar systems. Apply at the rate of 1 gallon per 7,500 –10,000 lbs. of fruit

Storage Wax Line Spray Application: Mix 64 - 128 fl. oz. of PHILABUSTER in 100 gallons of diluted storage wax and apply to fruit over conveyer rollers or brushes using T-jet, control droplet applicator (CDA), drip or similar systems. Apply at the rate of 1 gallon per 3,800 lbs. of fruit.

Periodically measure the concentration of the active ingredients in the treating solutions from drenchers, dip and wash tanks, and recovery spray systems to maintain the proper level of active ingredient. Aqueous applications must be applied prior to fruit receiving any wax applications.

Citrus fruit from the same lot may not receive more than two treatment combinations.

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, 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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* Pymimethanil manufactured by Bayer CropScience.