



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

APR 4 2008

RE: Notification of Company Name Change from Janssen Pharmaceutica Inc., to
Janssen Pharmaceutica, N.V.
EPA Reg. No.: 43813-38
Date of Submission: March 7, 2008

Dear Mrs. Haman-Hoy:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated March 7, 2008, for the product, Philabuster 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

	United States Environmental Protection Agency Washington, DC 20460	<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, a Division of Janssen Pharmaceutica, N.V. /43813-38	2. EPA Product Manager Mary Waller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Janssen PMP, a Division of Janssen Pharmaceutica, N.V./PHILABUSTER 400 SC	PM# 21	
5. Name and Address of Applicant (Include ZIP Code) 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	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"/> 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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NOTIFICATION
APR 4 - 2008

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

"Notification of Company Name Change from Janssen Pharmaceutica Inc. to Janssen PMP a Division of Janssen Pharmaceutica, N.V. per PR Notice 98-10." "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 <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product				<input type="checkbox"/> Lithograph Paper glued 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 <div style="border: 1px solid black; padding: 5px; text-align: center;">(Stamped)</div>
2. Signature 	3. Title Associate Regulatory Affairs	
4. Typed Name Joanne Haman-Hoy	5. Date March 7, 2008	

**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.

STORAGE AND DISPOSAL

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

PESTICIDE 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 - PLASTIC CONTAINERS: 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.

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.)

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. 43813-38

EPA EST. NO. 074263-DEU-001

Janssen PMP, a Division of Janssen Pharmaceutica, N.V.
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

DIRECTIONS FOR USE

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

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 PMP, a Division of Janssen Pharmaceutica, N.V. 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.**

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 PMP, a Division of Janssen Pharmaceutica, N.V. 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, a Division of Janssen Pharmaceutica, N.V. In no case shall Janssen PMP, a Division of Janssen Pharmaceutica, N.V. 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 PMP, A DIVISION OF JANSSEN PHARMACEUTICA, N.V. 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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* Pyrimethanil manufactured by Bayer CropScience.

