



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Joanne Haman-Hoy
Janssen PMP,
a Division of Janssen Pharmaceutica NV
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

MAY 22 2009

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4

Dear Ms. Haman-Hoy:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated May 4, 2009 for:

EPA Registration 43813-6

Fungaflor 500 EC

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN-2007-4. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Nicole Williams of my staff at 703-308-5551.

Sincerely,

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

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



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

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	United States Environmental Protection Agency 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 43813-6	2. EPA Product Manager Tony Kish	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) FUNGAFLOR 500 EC	PM# 22	
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. <u>MAY 22 2009</u> 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.)

"Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156, 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:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>HDPE</u>
* 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 checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1, 50, 264	5. Location of Label Directions <input type="checkbox"/> On Label
6. Manner in Which Label is Affixed to Product <input checked="" 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 (Stamped)
2. Signature 	3. Title Associate Regulatory Affairs	
4. Typed Name Joanne Haman-Hoy	5. Date May 4, 2009	

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Janssen PMP

FUNGAFLOR[®] 500EC

An Emulsifiable Concentrate for Post-harvest treatment of Citrus Fruits

ACTIVE INGREDIENT: (w/w)	
IMAZALIL: 1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl)-1H-imidazole*	44.6%
INERT INGREDIENTS: (w/w)	55.4%
TOTAL	100.0%

Contains 4.17 lbs. active ingredient/gal.

NOTIFICATION

KEEP OUT OF REACH OF CHILDREN

MAY 22 2009

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)

See side panel for additional precautionary statements

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 eye. -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 or clothing	-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.	

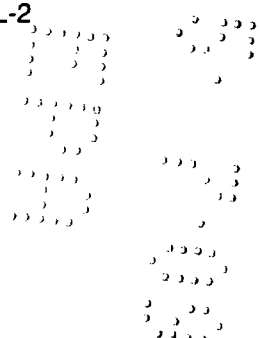
NET CONTENTS: 52.8 gal (200 L)

EPA REG. NO. 43813-6

EPA EST. NO. 43813-BL-2

JANSSEN PMP

a Division of Janssen Pharmaceutica NV
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200



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.

PERSONAL PROTECTIVE EQUIPMENT (PPE):

All mixers, loaders, applicators, and other handlers must wear:

- Protective eyewear (goggles, face shield, safety glasses)
- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical resistant gloves, except for bag sewers, seed planters, truck drivers, and sorters.
- Chemical resistant apron when mixing/loading, cleaning up spills, cleaning equipment, or otherwise exposed to the concentrate.

Some materials that are chemical-resistant to this product are butyl rubber, nitrile rubber, neoprene rubber, PVC, viton, or barrier laminate. If you want more options, follow the instructions for Category C on an EPA chemical-resistance category selection chart.

USER SAFETY REQUIREMENTS:

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS:
 Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
 Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
 Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This chemical is toxic to fish. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff from the treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when cleaning equipment or disposing of equipment wash waters or rinsate. Apply this product only as specified on the label.

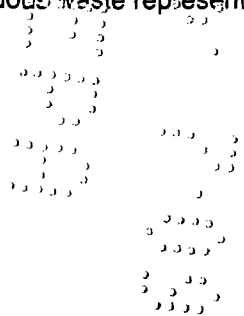
Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. 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.

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 Regional Office for guidance.



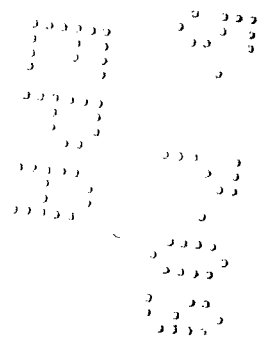
CONTAINER DISPOSAL

Non-refillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows:

[For containers \leq 5 gallons in size] - Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[For containers $>$ 5 gallons in size] - Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.



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DIRECTIONS FOR USE:

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

GENERAL PRECAUTIONS AND RESTRICTIONS:

Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application.

Application Restrictions for Citrus Drench:

Do not enter or allow others to enter the treatment area until the citrus is treated and completely drained. The windows and doors of the transport vehicle must be closed prior to and during treatment.

Citrus Fruits: Intended for post-harvest control of *Penicillium digitatum* (green mold), *Penicillium italicum* (blue mold), *Diaporthe citri* (phomopsis stem end rot), *Diplodia natalensis* (diplodia rot) and *Alternaria citri* on citrus fruits.

Used as directed, FUNGAFLOR 500EC has curative and preventative action as well as antispore properties.

DOSE RECOMMENDATIONS:

In dips, wash tanks, and drenchers: Apply FUNGAFLOR 500EC at rates of 12.8-19.2 fl. oz. per 100 gallons water (500-750 ppm active ingredient). The treatment solutions should be inspected periodically to insure the proper concentration of active ingredient. Length of dip time should not exceed two minutes.

In non-recovery spray: Apply FUNGAFLOR 500EC at 25.5 fl.oz. per 100 gal water (1000 ppm a.i.). Apply to freshly-cleaned citrus immediately prior to waxing.

For water spray brush application: After washing, apply FUNGAFLOR 500EC at 25.5 fl.oz. per 100 gal water (1000 ppm a.i.). Apply prior to storage wax application.

In citrus wax: Apply 51.1 fl.oz. of FUNGAFLOR 500EC to 100 gal of citrus wax (2000 ppm a.i.). Use without further dilution in conventional waxing equipment.

Remark 1: Combinations of above-listed treatments are possible, but never more than two treatments should be carried out on the same citrus lot.

Remark 2: In waxes, sporulation control can be obtained, at the rate of 102.2 fl.oz. FUNGAFLOR 500EC per 100 gallons citrus wax or diluted "ready to use" detergent material (4000 ppm a.i.). When this dilution is used, combinations of treatments are not allowed.

Remark 3: AFTER DILUTION OF FUNGAFLOR 500EC IN WAX, STIR THOROUGHLY FOR AT LEAST 15 MINUTES WITH A MIXING DEVICE AT 1500 RPM.

NOTICE OF WARRANTY

Janssen PMP, a Division of Janssen Pharmaceutica NV 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. To the extent permitted by law, Janssen PMP disclaims any liability for consequential, special or indirect damages resulting from the use or handling of this product. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, JANSSEN PMP MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

*Active Ingredient and formulation are manufactured by Janssen Pharmaceutica NV, B-2340 Beerse, Belgium
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