

43813-26

6/4/2009

1 of 5



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUN 4 2009

William R. Goodwine
Janssen PMP,
a Division of Janssen Pharmaceutica NV
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

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

Dear Mr. Goodwine:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated May 8, 2009 for:

- | | |
|------------------------------------|---------------------------|
| EPA Registration 43813-26 ✓ | Fungaflor 75 WSG |
| EPA Registration 43813-38 | Philabuster 400 SC |

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,

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

2085



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

	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 43813-26	2. EPA Product Manager Tony Kish	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) FUNGAFLOR 75 WSG	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. _____ NOTIFICATION Product Name _____ JUN 04 2009

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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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 type="checkbox"/> Other (Specify) _____ FIBER DRUM & PLASTIC LINER
* 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 2.2 & 55 LBS (1 & 25 KG)	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 William R. Goodwine	Title Sr Director, Regulatory Affairs & Product Development	Telephone No. (Include Area Code) (609) 730-2607
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 both under applicable law.		6. Date of Application Received (Stamped)
2. Signature 	3. Title Sr Director, Regulatory Affairs & Product Development	
4. Typed Name William R. Goodwine	5. Date May 8, 2009	

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NOTIFICATION

JUN 04 2009

FUNGAFLOR 75 WSG

Water Soluble Granule

For postharvest treatment of citrus fruits

ACTIVE INGREDIENT: (w/w)

IMAZALIL SULFATE:

1-(2-2,4-dichlorophenyl)-2-(2-propenyloxy)-ethyl)-1H-imidazole sulfate*100%

(*Equivalent to 75% imazalil base)

KEEP OUT OF REACH OF CHILDREN

DANGER

PELIGRO

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 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 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.
<p>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> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
<p>NOTE TO PHYSICIAN</p> <p>Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

NET CONTENTS: 2.2 lbs (1 KG)

EPA REG. NO. 43813-26

EPA EST. NO. 074690-DEU-001

Manufactured for:

JANSSEN PMP

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



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

DANGER PELIGRO

Corrosive. Causes irreversible eye damage. May be fatal if swallowed or inhaled. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Do not breathe dust.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical resistant to this product are listed below. If you want more options follow the instructions for Category A on the EPA chemical resistance category selection chart.

For handling activities, wear goggles or face shield, long-sleeved shirt and long pants, shoes, socks, chemical resistant gloves made of any waterproof material, such as natural rubber, polyethylene, PVC, neoprene rubber, nitrile rubber, or butyl rubber, and a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N, P, R, or HE filter.

USER SAFETY RECOMMENDATIONS

Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

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.

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 HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows:

[For plastic containers \leq 5 gallons in size] – Empty the remaining contents into application equipment or a mix tank. 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 fiber drums or paperboard containers with plastic liners $>$ 5 gallons in size] – Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment.

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.

