

43813-2

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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Ms Joanne Haman-Hoy  
Janssen PMP  
Division of Janssen Pharmaceutica N.V.  
1125 Trenton-Harbouton Road  
Titusville, NJ 08560-0200

JAN 30 2009

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

Dear Registrant:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated September 5, 2008 for:

**EPA Registration 43813-2 Fung<sup>g</sup>alor Technical**

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 Banza Djapao of my staff at 703-305-7269.

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

	United States <b>Environmental Protection Agency</b> 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**

<b>1. Company/Product Number</b> Janssen PMP, a Division of Janssen Pharmaceutica, N.V. /43813-2	<b>2. EPA Product Manager</b> C. Giles-Parker	<b>3. Proposed Classification</b> <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
<b>4. Company/Product (Name)</b> Janssen PMP, a Division of Janssen Pharmaceutica, N.V./FUNGAFLOR Technical	<b>PM#</b> 22	
<b>5. Name and Address of Applicant (Include ZIP Code)</b> 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	<b>6. Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: <div style="text-align: right; font-weight: bold; font-size: 1.2em;">NOTIFICATION</div> EPA Reg. No. _____ <b>JAN 30 2009</b> _____  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**

<b>1. Material This Product Will Be Packaged In:</b>				<b>2. Type of Container</b>	
<b>Child-Resistant Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Unit Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Water Soluble Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
<b>* Certification must be submitted</b>		If "Yes" Unit Packaging wgt.    No. per container	If "Yes" Package wgt    No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input checked="" type="checkbox"/> Other (Specify) <small>steel-plastic composite barrels</small>	
<b>3. Location of Net Contents Information</b>		<b>4. Size(s) Retail Container</b>		<b>5. Location of Label Directions</b>	
<input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		50 Liter		<input type="checkbox"/> On Label	
<b>6. Manner in Which Label is Affixed to Product</b>			<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.)

<b>Name</b> Joanne Haman-Hoy	<b>Title</b> Associate Regulatory Affairs	<b>Telephone No. (Include Area Code)</b> (609) 730-2609
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<b>Certification</b> 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.	<b>6. Date Application Received (Stamped)</b>     
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<b>2. Signature</b> 	<b>3. Title</b> Associate Regulatory Affairs	
<b>4. Typed Name</b> Joanne Haman-Hoy	<b>5. Date</b> September 5, 2008	

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# FUNGAFLOR™ Technical

**ACTIVE INGREDIENT:** (w/w)

Imazalil: 1-[2-(2,4-dichlorophenyl)

-2-(2-propenyloxy)ethyl]-1H-imidazole\*\* 98.94 %

**OTHER INGREDIENTS** 1.06 %

**TOTAL** 100.00 %

**NOTIFICATION**

JAN 30 2009

FOR MANUFACTURING USE ONLY

**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)

<b>FIRST AID</b>	
<b>If in eyes</b>	-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.
<b>If swallowed</b>	-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.
<b>If on skin or clothing</b>	-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.
<b>HOT LINE NUMBER:</b>	
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.	
<b>NOTE TO PHYSICIAN</b>	
Probable mucosal damage may contraindicate the use of gastric lavage.	

NET Contents: 110 lbs./50 Kgs.

EPA Reg. No. 43813-2

EPA Est. No. 43813-BL-2

**JANSSEN PMP**

a Division of Janssen Pharmaceutica NV

1125 Trenton-Harbourton Road

Titusville, NJ 08560-0200

\*\*Active ingredient is manufactured by Janssen Pharmaceutica N.V., B-2340 Beerse, Belgium.

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**NOTIFICATION**

JAN 30 2009

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

**DANGER**

Corrosive. Causes irreversible eye damage. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes, or on clothing. Avoid contact with skin. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

Wear goggles or face shield. Wear protective clothing and chemical resistant gloves made of any waterproof material. Wash thoroughly with soap and water after handling. 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.

Only for formulation into a fungicide for the following uses: seed treatment of wheat and barley seed and postharvest application to citrus fruits. This product may be used to formulate products for any additional uses not listed on the manufacturing product label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses. Each formulator is responsible for obtaining EPA registration for his end use product(s).

**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 EPA Regional Office for guidance.

**CONTAINER DISPOSAL**

Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse (or equivalent). Offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**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. 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.

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