43813-4 1/8/2010 1/5

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAN 8 2010

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

Subject: Label Notification for Pesticide Registration Notice 2007-4
(EPA Registration Number 43813-4)

Dear Mr. Goodwine,

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated August 10, 2009 and your label resubmission dated January 5, 2010 for the product FUNGAFLOR® 75 SP (EPA Registration Number 43813-4). The Registration Division (RD) has conducted its review of this request for its applicability under PRN 2007-4 and finds that the label changes requested fall within the scope of PRN 2007-4. The label submitted with the application has been 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 call me directly at 703-305-6249 or Steve Schaible of my staff at 703-308-9362.

Sincerely,

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

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
43813-4	Tony Kish	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
FUNGAFLOR 75 SP	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

[ ] *Check if this is a new address*

6. Expedited Reveiw. 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

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

NOTIFICATION

JAN - 8 2010

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	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [xxxxxxx] Other (Specify) PLASTIC LINED FIBER DRUM
* *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	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	44 LBS (20 KG)	On Label

6. Manner in Which Label is Affixed to Product [xxxxx] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
William R. Goodwine	Senior Director, Regulatory Affairs & Product Development	(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 knowlingly 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
William R. Goodwine	Senior Director, Regulatory Affairs & Product Development
4. Typed Name	**5. Date**
William R. Goodwine	August 10, 2009

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

FUNGAFLOR® 75 SP

Soluble powder for manufacturing use only

ACTIVE INGREDIENT: (w/w)
Imazalil sulfate: 1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy) ethyl)-1H-imidazole sulfate* 100%

(Equivalent to 75% Imazalil base) NET CONTENTS: 110 lbs (50 kg)

KEEP OUT OF REACH OF CHILDREN

DANGER

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.

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.

EPA REG. NO. 43813-4 EPA EST. NO. 43813-BL-2

JANSSEN PMP
a Division of Janssen Pharmaceutica NV
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PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

DANGER

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 prefilter.

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.

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.

DIRECTIONS FOR USE
It is a violation of federal law to use this product in a manner inconsistent with its labeling.

This product may be used to formulate fungicide products for post harvest citrus and wheat and barley seed dressing applications. For specific uses not listed on the manufacturing use product label, this product may be used for formulation purposes providing the formulator or user group has complied with U.S. EPA data submission requirements regarding the 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 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: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows:

[For plastic containers ≤ 5 gallons in size] – Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ 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, triple rinse directions do not apply. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of in the same manner. If drum is contaminated and cannot be reused, dispose of in the same manner.

*Active Ingredient manufactured by Janssen Pharmaceutica NV
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