



43813-26

1-7-2005

1/7

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 |
|--|---|--|-----------------------|

Application for Pesticide - Section I

| | | |
|---|---|---|
| 1. Company/Product Number Janssen Pharmaceutica/43813--26 | 2. EPA Product Manager Cynthia Giles-Parker | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Janssen Pharmaceutica/FUNGAFLOR 75 WSG | PM# 22 | |
| 5. Name and Address of Applicant (Include ZIP Code) Janssen Pharmaceutica 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. |
|--|---|

NOTIFICATION
 JAN - 7 2005

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

Label Change: Add "Use of FUNGAFLOR 75 WSG should be integrated into an overall disease management program within each packinghouse"

Delete the word "pre" under personal protection equipment. "Pre" filter not required since FUNGAFLOR 75 WSG is a solid/granule and not a liquid or gas (per Label Manual, Section 10, Table 4).

Section - III

| | | | |
|--|--|---|---|
| 1. Material This Product Will Be Packaged In: | | | |
| Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container | Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt No. per container | 2. Type of Container <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 | | | |
| 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 <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | | |

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 Regulatory Affairs Associate | 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) <div style="border: 1px solid black; height: 40px; width: 100%;"></div> |
| 2. Signature | 3. Title Regulatory Affairs Associate | |
| 4. Typed Name Joanne Haman-Hoy | 5. Date 12/16/04 | |

Janssen Pharmaceutica Inc.

FUNGAFLO 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. |

HOT LINE NUMBER: Chem Trec: (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: 55 lbs (25 KG)

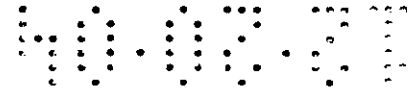
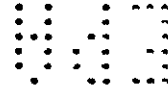
EPA REG. NO. 43813-26

EPA EST. NO. 074690-DEU-001

JANSSEN Pharmaceutica
1125 Trenton-Harbourton Rd.
Titusville, NJ 08560-0200

NOTIFICATION

JAN - 7 2005



2/2

**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.

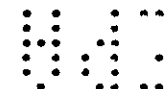
PESTICIDE STORAGE: Store in a cool dry place in the original container away from food and feed.

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 DISPOSAL: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

TM Trademark of Janssen Pharmaceutica Inc.

Rev 12/04



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.

FUNGAFLOR 75 WSG is formulated for aqueous application only; not compatible with storage or shipping waxes. Used as directed, FUNGAFLOR 75 WSG has curative and preventative action as well as anti-sporulation properties. Use of FUNGAFLOR 75 WSG should be integrated into an overall disease management program within each packinghouse.

DOSE RECOMMENDATIONS:

In dips, wash tanks, and drenchers: Weigh out 9 - 13.5 ounces of FUNGAFLOR 75 WSG and dissolve in 100 gallons of water to give a treating rate of 500-750 ppm of active ingredient. The treatment solutions should be monitored to insure the proper concentration of FUNGAFLOR. Length of dip time should not exceed two minutes.

In non-recovery spray & water spray brush application: Dissolve 18 ounces of FUNGAFLOR 75 WSG in 100 gallons of water to achieve a concentration of 1000 ppm FUNGAFLOR active ingredient. Apply to freshly cleaned citrus prior to waxing.

Remark

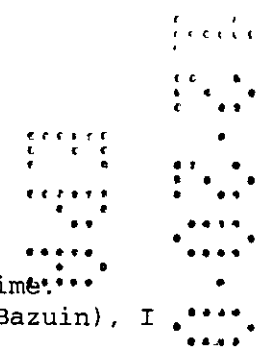
Combinations of above-listed treatments are possible, but never more than two (2) treatments should be carried out on the same citrus lot.

NOTICE OF WARRANTY

Janssen Pharmaceutica 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 Pharmaceutica. In no case shall Janssen Pharmaceutica 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 PHARMACEUTICA MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

400531

From: Hobgood.Sherada@epamail.epa.gov
[mailto:Hobgood.Sherada@epamail.epa.gov]
Sent: Monday, December 13, 2004 7:16 PM
To: BGoodwi@JANUS.JNJ.com
Cc: Bazuin.John@epamail.epa.gov
Subject: Fw: Clarification of Notification



Hi...Mr. Goodwin,
My apology in not answering your voice mail message in time...
Because you have had this cleared at the PM level (John Bazuin), I
would have no choice but to find the labeling changes
acceptable.....even though in reviewing the changes....I, too, would
have found them acceptable as a notification change pursuant to PR
Notice 98-10. So, do proceed.

Sherada D. Hobgood
Acting Ombudsperson
Registration Division (7505C)
Office of Pesticide Programs; OPPTS/U.S. EPA
phone: 703-308-8893
fax: 703-305-6920
email: Hobgood.Sherada@epa.gov

----- Forwarded by Sherada Hobgood/DC/USEPA/US on 12/13/2004 06:44 PM

"Goodwine, Bill
[JANUS]"
<BGoodwi@JANUS.J
To
NJ.com>

Sherada Hobgood/DC/USEPA/US@EPA
cc

12/13/2004 04:01
PM

Subject
Clarification of Notification

Sherada,
I am following up on an earlier voice mail message requesting your view
on whether 2 label changes on our FUNGAFLOR 75 WSG would be considered
a
Notification or Amendment. I reviewed these with Mr. John Bazuin who
was of the opinion, as I am, that these are Notications. I have
attached a label with the handwritten changes for your convenience.
In summary, I would like to:
1) add the following sentence to the label as requested by AZ for state
registration:
"Use of FUNGAFLOR 75 WSG should be integrated into an overall disease
management program within each packinghouse."
and
2) delete the word "pre" under personal protective equipment. This is
a
clear error correction per the Label Manual, Section 10, Table 4.
Since

FUNGAFLOR 75WSG is a solid/granule and not a liquid or gas, a "pre"
filter is not required.

Please advise so I may proceed with the appropriate action.

Regards,

Bill

<<Fungaflo.pdf>>

William R. Goodwine

Senior Director

Plant & Material Protection Division

Janssen Pharmaceutica Inc.

1125 Trenton-Harbourton Rd.

Titusville, NJ 08560

Tel/609-730-2607

Fax/609-730-2411

bgoodwi@janus.jnj.com (See attached file: Fungaflo.pdf)

JANSSEN



PHARMACEUTICA INC.

7/7

December 16, 2004

Cynthia Giles-Parker
Product Manager (22)
Fungicide Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
Office of Pesticide Programs
Washington, D.C. 20460

RE: FUNGAFLOR® 75 WSG (EPA Reg. No. 43813-26)
Notification of Label Change

Dear Ms. Giles-Parker,

Attached is form 8570-1 notifying EPA that Janssen Pharmaceutica wishes to make the following 2 changes to the FUNGAFLOR® 75 WSG label (copy enclosed with changes highlighted):

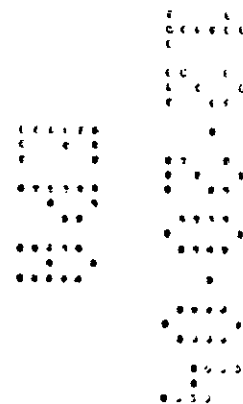
- Addition of the following sentence:
"Use of FUNGAFLOR 75 WSG should be integrated into an overall disease management program within each packinghouse"
- Delete the word "pre" under personal protective equipment. This was in error as FUNGAFLOR 75 WSG is a solid/granule and not a liquid or gas. Consequently, a "pre" filter is not required as per the Label Manual, Section 10, Table 4.

Also included is a copy of e-mail correspondence to Bill Goodwine from Sherada Hobgood, Acting Ombudsperson, concurring that these label changes are acceptable as a notification.

Please contact me at (609) 730-2609 should you require any additional information.

Sincerely,

Joanne Haman-Hoy
Regulatory Affairs Associate
Plant & Material Protection Division



1125 TRENTON-HARBOURTON ROAD
POST OFFICE BOX 200
TITUSVILLE, NEW JERSEY 08560-0200
(609) 730-2000

us.janssen.com