



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAY 3 2004

William R. Goodwine
Janssen Pharmaceutica Inc.
1125 Trenton-Harbourton Road
Post Office Box 200
Titusville, New Jersey 08560-0200

Subject: Fungaflor 75 WSG
EPA Registration Number 43813-26
Your label amendment application dated April 15, 2004

Dear Mr. Goodwine,

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is acceptable, provided that you comply with the following conditions.

1. Make the following change to the label.

* On the second page, change the heading "PRECAUTIONARY STATEMENT" to "PRECAUTIONARY STATEMENTS".

2. Submit one copy of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration may be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

2/5

If you have any questions about this letter, please contact John Bazuin at (703)305-7381.

Sincerely yours,



Cynthia Giles-Parker
Product Manager (22)
Fungicide Branch
Registration Division (7505C)

Attachment: Label stamped "ACCEPTED with COMMENTS"

Janssen Pharmaceutica Inc.

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.
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

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

MAY 3, 2004

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.**

43813-26

3/5

**PRECAUTIONARY STATEMENT
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 pre-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.

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5/17

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.

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.

0/5