



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

APR - 3 2003

Jeanne Haman-Hoy  
Janssen Pharmaceutica Inc.  
1125 Trenton-Harbourton Road  
Post Office Box 200  
Titusville, New Jersey 08560-0200

Subject: Fungaflor 500EC  
EPA Registration Number 43813-6  
Your label amendment application dated December 17,  
2002

Dear Ms. Haman-Hoy,

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 changes to the label.

a. The second to the last sentence in the "HAZARDS TO HUMANS & DOMESTIC ANIMALS" section ends with "...and before eating or smoking." This must be changed to "...and before eating, drinking or using tobacco."

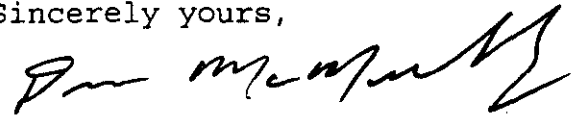
b. In the "ENVIRONMENTAL HAZARDS" section delete the last sentence ("Apply this product only as specified on this label").

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.

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

Sincerely yours,



Dennis McNeilly  
Acting Product Manager (22)  
Fungicide Branch  
Registration Division (7505C)

Attachment: Label stamped "ACCEPTED with COMMENTS"

Janssen Pharmaceutica

# FUNGAFLOR® 500EC

An Emulsifiable Concentrate for Post-harvest treatment of Fruits  
Containing 4.17 lbs. active ingredient/gal.

ACTIVE INGREDIENT: (w/w)	
IMAZALIL: 1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl)-1H-imidazole*	44.6%
INERT INGREDIENTS: (w/w)	55.4%
TOTAL	100.0%

**KEEP OUT OF REACH OF CHILDREN**

## WARNING

See side panel for additional precautionary statements

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.
<b>HOT LINE NUMBER:</b> Chem Trec: (800) 424-9300	
Have the product container 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: 25 L

EPA REG. NO. 43813-6

EPA EST. NO. 43813-EL-2

**ACCEPTED**  
with **COMMENTS**  
In EPA Letter Dated:  
**APR 3 2003**

**JANSSEN Pharmaceutica Inc.**  
Plant and Material Protection Division  
1125 Trenton-Harbourton Road  
Titusville, NJ 08560-0200

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

43813-6

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

## WARNING

May be fatal if swallowed. Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse.

## ENVIRONMENTAL HAZARDS

For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment, or disposal of wastes. Apply this product only as specified on this label.

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:

Notice to User: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

## STORAGE AND DISPOSAL

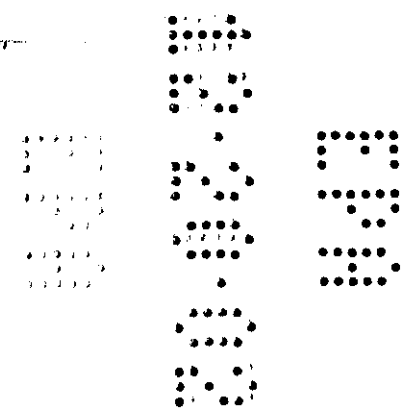
**PROHIBITIONS:** Do not contaminate water, food, or feed by storage or disposal.

**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 Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

\*\*Active ingredient and formulation are manufactured by Janssen Pharmaceutica,  
B-2340 Beerse, Belgium  
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12/02



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.

Used as directed, FUNGAFLO 500EC has curative and preventative action as well as antispore properties.

**DOSE RECOMMENDATIONS:**

In dips, wash tanks, and drenchers: Apply FUNGAFLO 500EC at rates of 2.8-19.2 fl. oz. per 100 gallons water (500-750 ppm active ingredient). The treatment solutions should be inspected periodically to insure the proper concentration of active ingredient. Length of dip time should not exceed two minutes.

In non-recovery spray: Apply FUNGAFLO 500EC at 25.5 fl.oz. per 100 gal water (1000 ppm a.i.). Apply to freshly-cleaned citrus immediately prior to waxing.

For water spray brush application: After washing, apply FUNGAFLO 500EC at 25.5 fl.oz. per 100 gal water (1000 ppm a.i.). Apply prior to storage wax application.

Foamer - Apply FUNGAFLO 500EC at 51.1 fl. oz. per 100 gal of diluted "ready to use" detergent material (2000 ppm a.i.). Apply to citrus from a mechanical foamer. Use only as much as needed to clean fruit.

In citrus wax: Apply 51.1 fl.oz. of FUNGAFLO 500EC to 100 gal of citrus wax (2000 ppm a.i.). Use without further dilution in conventional waxing equipment.

Remark 1: Combinations of above-listed treatments are possible, but never more than two treatments should be carried out on the same citrus lot.

Remark 2: In waxes and foams, sporulation control can be obtained, at the rate of 102.2 fl.oz. FUNGAFLO 500EC per 100 gallons citrus wax or diluted "ready to use" detergent material (4000 ppm a.i.). When this dilution is used, combinations of treatments are not allowed.

Remark 3: AFTER DILUTION OF FUNGAFLO 500EC IN FOAM OR WAX, STIR THOROUGHLY FOR AT LEAST 15 MINUTES WITH A MIXING DEVICE AT 1500 RPM.

**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 OF IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

