



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MAR 4 2005

William Goodwine  
Janssen Pharmaceuticals Inc.  
Plant & Material Protection Division  
11125 Trenton-Harbourton Rd.  
Titusville, NJ 08560

Subject: Fungalor 500 EC  
EPA Registration No. 43813-6  
Your Label Amendment applications dated September 17, and December 13,  
2004

Mr. Goodwine:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable subject to the comments listed below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

1. The equivalent Spanish signal word "Aviso" is required to appear in close proximity of the English signal word "Warning". Additionally, this statement must be included: "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)."
2. Under Precautionary Statements:
  - a.) Revise the paragraph under this heading by deleting all but the first two (2) sentences, and then adding the following text: "Do not get in eyes or on clothing. Avoid contact with skin."
  - b) Following the previous paragraph, add:  
"Handler Personal Protective Equipment (PPE): Applicators and other handlers must wear:
    - long sleeved shirts, and long pants
    - protective eyewear
    - socks and shoes"
  - c) Also add: "Follow the manufacturers" instructions for cleaning/ maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep

and wash PPE separately from other laundry.”

d) Add the following statements, in a box format:

“Users should wash hands before eating, drinking, chewing gum, using tobacco, and using the toilet.”

3. Under “Agricultural Use Requirements” revise the PPE for early entry as follows: “coveralls and chemical resistant gloves (made of any water proof material)”.

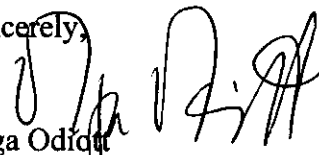
4. You may delete the Non-Agricultural Use Requirements box.

5. Move the Storage and Disposal statements to the end of the Directions for Use section. This way the break between the heading Directions for Use and the body of the use directions is eliminated.

6. Under the section Disclaimer of Warranties revise the statement beginning with: “In no case shall Janssen Pharmaceutica...” to read: “To the extent permitted by law Janssen Pharmaceutica disclaims any liability for consequential...” As currently written the statement negates and/or detracts from labeling requirements as set forth by the Agency in 40 CFR Part 156, and is, therefore, considered misbranding.

If you have any questions, please contact Bryant Crowe by phone at (703) 305-0025 or via email at [crowe.bryant@epa.gov](mailto:crowe.bryant@epa.gov).

Sincerely,



Olga Odott  
Acting Product Manager (22)  
Fungicide Branch  
Registration Division (7505C)

Enclosure

3/6

Janssen Pharmaceutica

# FUNGAFLOR® 500EC

An Emulsifiable Concentrate for Post-harvest treatment of Citrus Fruits and Wheat and Barley Seed Treatment

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%

Contains 4.17 lbs. active ingredient/gal.

**KEEP OUT OF REACH OF CHILDREN**

## WARNING

See side panel for additional precautionary statements

FIRST AID	
<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 inhaled</b>	-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.
<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> 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: 52.8 gal (200 L)

EPA REG. NO. 43813-6

EPA EST. NO. 43813-BL-2

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

**ACCEPTED**  
**with COMMENTS**  
 In EPA Letter Dated:  
**MAR 4 2005**

Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act,  
 this pesticide has been found to  
 meet the requirements of FIFRA, Reg. No.  
 43813-6

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4/6

**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, drinking or using tobacco. 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.

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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12/04

**DIRECTIONS FOR USE:**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours. Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated such as plants, soil, or water is: coveralls, chemical-resistant gloves, such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride or viton, shoes plus socks, and protective eyewear.

**Non-AGRICULTURAL USE REQUIREMENTS**

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

**Citrus Fruits:** 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, FUNGAFLOR 500EC has curative and preventative action as well as antisporeulation properties.

**DOSE RECOMMENDATIONS:**

**In dips, wash tanks, and drenchers:** Apply FUNGAFLOR 500EC at rates of 12.8-19.2 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 FUNGAFLOR 500EC at 25.5 fl.oz. per 100 gal water (1000 ppm a.i.). Apply to freshly-cleaned citrus immediately prior to waxing.

6/6

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

**In citrus wax:** Apply 51.1 fl.oz. of FUNGAFLOR 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, sporulation control can be obtained, at the rate of 102.2 fl.oz. FUNGAFLOR 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 FUNGAFLOR 500EC IN FOAM OR WAX, STIR THOROUGHLY FOR AT LEAST 15 MINUTES WITH A MIXING DEVICE AT 1500 RPM.

**WHEAT & BARLEY:** For control of barley leaf stripe, seedborne net blotch and *Septoria nodorum*, and protection against the seed and soilborne phases of the common root rot disease complex (*Helminthosporium*, *Fusarium*). Promotes stand establishment by protecting against seed and seedling blights caused by *Helminthosporium*, *Fusarium*, or *Penicillium*.

FUNGAFLOR 500 EC should be diluted with sufficient water to insure adequate coverage to the seed. Apply by standard mechanical slurry or mist-type seed treatment equipment.

**DOSE RECOMMENDATIONS** Use 0.17 – 0.3 fl. oz. (5 – 9 mL) FUNGAFLOR 500 EC per 100 lbs. seed. Use the higher dose when disease pressure is severe.

**SEED LABELING:** Seeds treated with FUNGAFLOR 500 EC. Do not use treated seed for food, feed or oil purposes. Do not graze or feed livestock on treated areas for six weeks after planting.

**USE PRECAUTION:** All seed treated with this product must be adequately dyed. Any dye added to treated seed must be cleared for use under 40 CFR, Part 180.1001.

**NOTE TO USER:** Combination treatments of FUNGAFLOR 500 EC with products containing lindane may result in delayed emergence and stunting of wheat and barley, however, plants will usually outgrow this effect. Do not carry over seed treated with lindane to the next crop season. Minimize time between treating and planting for such treatments.

### 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.