



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Joanne Harman-Hoy
Regulatory Affairs Associate
Plant/Material Protection Division
Janssen Pharmaceutica Inc.
P.O. Box 200
Titusville, NJ 08560-0200

MAY - 8 2003

Subject: Fungaflor™ Technical
EPA Reg. No. 43813-2
Your amendment dated March 4, 2003

Dear Ms Harman-Hoy:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended is acceptable provided the following changes are made:

1. In the list of ingredients, change "INERT INGREDIENTS" to "OTHER INGREDIENTS"
2. In the First Aid block, move the "If in eyes" section above the "If swallowed" section.
3. Change the header "PRECAUTIONARY STATEMENT" to "PRECAUTIONARY STATEMENTS"
4. In the "HAZARDS TO HUMANS AND DOMESTIC ANIMALS" section:
 - change "rubber gloves" to "chemical resistant gloves made of any waterproof material."
 - Include the sentence "Wash thoroughly with soap and water after handling."
5. In the "DIRECTIONS FOR USE" section remove the comma from the text "...use product label if the formulator..."
6. In the "STORAGE AND DISPOSAL" section, change the header "STORAGE" to "PESTICIDE STORAGE."

Fungaflor™ Technical
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- 7. In the "CONTAINER DISPOSAL" section, add the word "by" to the phrase "sanitary landfill, or (by) incineration..."
- 8. In the "GENERAL" section, either delete the section or reword the instructions so that it is clear what "approved alternatives" refers to.

One copy of the label stamped "Accepted with comments" is enclosed for your records.

Please submit one copy of the final printed label before the product is released for shipment.

If you have any questions, please contact Robert Westin by phone at (703) 305-5721 or via email at westin.robert@epa.gov.

Sincerely,



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

enclosure

FUNGAFLOR™ Technical

ACTIVE INGREDIENT: (w/w)

Imazalil: 1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-1H-imidazole** 98.94 %

INERT INGREDIENTS 1.06 %

TOTAL 100.00 %

For use in formulating products for seed treatment of wheat and barley and for post-harvest application to citrus fruits.

KEEP OUT OF REACH OF CHILDREN

DANGER

| FIRST AID | |
|--|--|
| 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 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 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. |
| 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. |
| 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: 110 lbs./50 Kgs.

EPA Reg. No. 43813-2

EPA Est. No. 43813-BL-2

JANSSEN PHARMACEUTICA Inc.

Plant and Material Protection Division
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200
U.S.A.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

MAY 8 2003

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

43813-2

**PRECAUTIONARY STATEMENT
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER

Corrosive. Causes irreversible eye damage. May be fatal if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear goggles or face shield. Wear protective clothing and rubber gloves. Wash hands 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.

This product may be used to formulate products for specific uses not listed on the manufacturing use product label, if 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.

STORAGE

Store in a cool dry place.

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

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.

GENERAL

Consult Federal, State, or Local Disposal Authorities for additional restrictions and approved alternatives.

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.

**Active ingredient is manufactured by Janssen Pharmaceutica N.V., B-2340 Beerse, Belgium.

U.S. PAT. NO. 3,658,813

02/03

