

43813-14

05/07/2003

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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 - 7 2003

Subject: Fecundal® 100EC
EPA Reg. No. 43813-14
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 ingredients list, change "Inert Ingredients" to "Other Ingredients"
2. In the Spanish warning statement, change "ta" to "la" in the phrase "...para que se ta (la) explique...."
3. In the section PERSONAL PROTECTIVE EQUIPMENT, add the phrase "made of any waterproof material" immediately after "chemical-resistant gloves"
4. Under "USER SAFETY RECOMMENDATIONS" delete the apostrophe from the first word of text.
5. In the NOTICE OF WARANTEE section, in the last two lines change the word "of" to "or" (two occurrences).
6. In the STORAGE AND DISPOSAL section:
 - Change the header "STORAGE" TO "PESTICIDE STORAGE"
 - under Container Disposal, add the word "by" to the phrase "...sanitary landfill, or (by) incineration...."

Fecundal® 100EC

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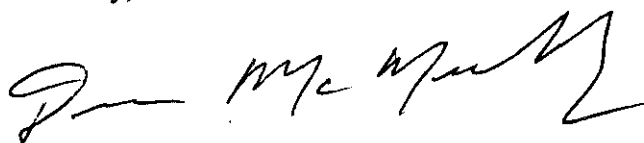
7. Change the header "SEED LABELLING" to "SEED LABELING"

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

JANSSEN PHARMACEUTICA
FECUNDAL® 100EC
Seed Treatment

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

ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAY 7 2003

Active Ingredient

Imazalil: 1-(2-(2,4-dichlorophenyl)-2
(2-propenyloxy)ethyl)-1H-imidazole* 9.5%

Inert Ingredients 90.5%

Total 100.0%

Contains 0.84 lbs. of Imazalil per gallon

43813-14

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

Si usted no entiende, busque a alguien para que se ta explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

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 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 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.
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: 5 gallons

EPA Reg. No. 43813-14

EPA Est. No. 43813-BL-2

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

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

DANGER PELIGRO

Corrosive. Causes irreversible eye damage. Harmful if swallowed or absorbed through skin. Do not get in eyes, or on clothing. Avoid contact with skin. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

PERSONAL PROTECTIVE EQUIPMENT:

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart. Applicators and other handlers must wear long-sleeved shirt and long pants, chemical-resistant gloves, such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride or viton, shoes plus socks, and protective eyewear. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS:

User's should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS:

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.

NOTICE OF WARRANTY

Treatment of highly mechanically damaged seed of known low vigor and poor quality, except for the purpose of curative control of existing disease or insect pests, can result in reduced germination and/or reduction of seed and seedling vigor. Treat and germination test a sample of the seed lot before treating with a selected chemical treatment. Excess seed should not be carried over from one season to the next without re-testing germination. Due to seed quality conditions beyond the control of Janssen Pharmaceutica, no claims are made to guarantee germination of carry-over seed.

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 OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OF IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

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.

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 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. If this is a returnable container, please return it directly to the manufacturer.

DOSE RECOMMENDATIONS:

FECUNDAL 100EC may be applied directly to the seed using standard mechanical slurry or mist-type seed treatment equipment and may be diluted with water to improve coverage.

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*. Use 0.8 to 1.5 fl. oz. FECUNDAL 100EC per 100 lbs. seed. Use the higher dose when disease pressure is severe.

SEED LABELLING: Seeds treated with FECUNDAL 100EC. 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 FECUNDAL 100EC 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.

*Active ingredient is manufactured by Janssen Pharmaceutica, Beerse, Belgium.

01/2003

