



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 1, 1996

Mr. William R. Goodwine
Janssen Pharmaceutica
Plant Protection Division
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

SUBJECT: Submission of Label Amendment
EPA Reg. No. 43813-3; Fecundal 10 EC
Your Letter Dated December 21, 1995

Dear Mr. Goodwine:

The labeling referred to above and submitted in connection with the registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, subject to the following comments:

WHAT THIS ACCEPTANCE MEANS:

Based on your certification, the Agency has accepted the labeling changes that are necessary to comply with the Worker Protection Standard (WPS) labeling requirements of 40 CFR §156 Subpart K described in PR Notices 93-7 and 93-11. Any other labeling changes submitted in connection with this amendment application but not directly related to compliance with the WPS have not been reviewed or accepted by the Agency. If you wish to make such changes, you must submit a separate amendment application proposing them. If your product is currently suspended, the acceptance of this labeling amendment does not affect the suspension in any way.

WHAT YOU NEED TO DO NEXT:

By the next label printing, make all the specified changes to your labeling and send one (1) copy of the final printed labeling to EPA:

- BEFORE selling or distributing any product bearing the final printed labeling and within one year, and

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- WITHIN one year from date of this acceptance.

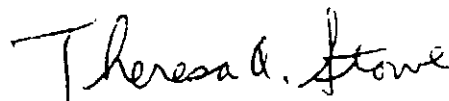
Change the IF SWALLOWED statement, to be consistent with the precautionary labeling of similar products, as follows:

IF SWALLOWED: Call a physician or poison control center. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. Get medical attention. NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

A copy of your proposed labeling stamped "ACCEPTED WITH COMMENTS" is enclosed for your file.

If you have any questions, please contact me at (703) 305-7740.

Sincerely yours,



Theresa A. Stowe
Acting Product Manager (22)
Fungicide-Herbicide Branch
Registration Division (7505C)

Encl:

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**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 G 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 or viton, shoes plus socks, and protective eyewear. 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.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

JANSSEN PHARMACEUTICALS

FECUNDAL®

Seed Treatment

Active Ingredient

Imazalil: 1-(2-(2,4-dichlorophenyl)-2

(2-propenyloxy)ethyl)-1H-imidazole*

Inert Ingredients

Total

Contains 0.86 lbs. of Imazalil per gallon

EPA Reg. No. 43813-3

EPA Est. No. 43813-BL-2

KEEP OUT OF REACH OF

DANGER

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

STATEMENT OF PRACTICAL USE

IF IN EYES: Call a physician. Hold eyelids open and flush with water for 15 minutes.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF SWALLOWED: Induce vomiting, pump stomach, call a physician.

IF INHALED: See a physician if an abnormal reaction occurs.

See side panel for additional precautionary statements.

Net Contents: 5 gallons

* Active ingredient is manufactured by Janssen Pharmaceutica



Janssen Pharmaceutica
Plant Protection Division
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200
(609) 730-2607

Under the
Fungicide
as amended
register

h/h

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 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 rinse 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 10EC may be applied directly to the seed using standard mechanical dry 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 soilborne 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 10EC per 100 lbs. seed. Use the higher dose when disease pressure is severe.

SEED LABELLING: Seeds treated with FECUNDAL 10EC. 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 10EC 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

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.