

# U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Antimicrobials Division (7510C) 1200 Pennsylvania Avenue NW Washington, D.C. 20460

Term of Issuance:	

Date of Issuance:

June 6, 2006

EPA Reg. Number:

43813-33

Conditional

Name of Pesticide Product:

NOTICE OF PESTICIDE:

x Registration

\_\_ Reregistration

_			
Betho	guard¹	™ Тес	hnical

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Janssen Pharmaceutica, Inc. 1125 Trenton-Harbourton Road Titusville, NJ 08560-0200

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(C) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
- 2. Make the labeling changes listed below before you release the product for shipment:
  - a. Revise the "EPA Registration Number to read, "EPA Reg. No. 43813-33".

Signature of Approving Official:	Date:	
10		
Adam Heyward		
Product Manager Team-34		
Regulatory Management Branch II	June 6, 2006	
Antimicrobials Division (7510C)		

2/5

- b. Under the environmental hazard statement, add the following the following sentence at the beginning of the statement:
  - " This product is toxic to fish and aquatic invertebrates."
- c. Under the Directions For Use heading, add the following the following statement:
  - " Not for use in food grade paper, paperboard, paper coating and adhesive "
- d. Under the Directions For Use, add the following the following statement:
  - " Not for use in Textiles used in clothing items."
- 3. Submit the following data, conducted under the conditions of the Good Laboratory Practice (GLP) Standards by the date specified below:

Acute Freshwater Fish Toxicity Study	850.1075	30-Sept-2006
Acute Freshwater Invertebrate Toxicity Study	850.1300	30-Sept-2006
21-Day Inhalation Study	870.3465	30-April-2007

4. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Adam Heyward

Product Manager 34

Regulatory Branch II

Antimicrobials Division (7510P)

Enclosure: (Stamped Label)

## **CENTER PANEL**

Janssen Pharmaceutica

## BETHOGUARD™ TECHNICAL

Biocide For Manufacturing Use Only

For use in formulating material preservative products

ACTIVE INGREDIENT: (w/w)

BETHOXAZIN:

#### KEEP OUT OF REACH OF CHILDREN

### **DANGER**

See side panel for additional precautionary statements

NET CONTENTS: 55 pounds (25 kilograms)

EPA REG. NO. 43813-XX EPA EST. NO. 43813-XX-XX



JANSSEN
Pharmaceutica, Inc.
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

™Trademark of Janssen Pharmaceutica Inc.

ACCEPTED with COMMENTS EPA Letter Dated:

JUN - 6 2006

Under the Federal Insecticide.
Fungicide, and Rodenticide Act as amended for the pesticide, registered under EPA Reg. No. 43813-33



## **LEFT PANEL**

## PRECAUTIONARY STATEMENT HAZARDS TO HUMANS & DOMESTIC ANIMALS

#### DANGER

Corrosive. Causes irreversible eye damage. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing (long sleeved shirt, long pants, socks, and safety shoes) and impervious gloves (nitrile rubber or neoprene). Harmful if swallowed or inhaled. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

#### STATEMENT OF PRACTICAL TREATMENT

FIRST AID				
IF IN EYES	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center, or doctor, or 1-800-424-9300 immediately for treatment advice.</li> </ul>			
IF ON SKIN OR CLOTHING	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center, or doctor, or 1-800-424-9300 immediately for treatment advice.</li> </ul>			
IF SWALLOWED	<ul> <li>Call a poison control center, or doctor, or 1-800-424-9300 immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>			
IF INHALED	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>Call a poison control center, or doctor, or 1-800-424-9300 immediately for treatment advice.</li> </ul>			
	HOT LINE NUMBER 1-800-424-9300			
Have the product container with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information				
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.				

### USER SAFETY RECOMMENDATIONS

Users 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.
- Users should remove personal protective equipment immediately after handling this product. Wash outside of
  gloves before removing. As soon as possible, wash thoroughly.
- Follow manufacturers' instructions for cleaning and maintaining personal protective equipment (PPE). If no such
  instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other
  laundry

#### **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.



## **RIGHT PANEL**

#### DIRECTIONS FOR USE:

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

**GENERAL INFORMATION:** BETHOGUARD Technical is an anti-microbial agent to be used for the formulation of material preservative end use products that are registered with the U.S. Environmental Protection Agency.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

**PESTICIDE STORAGE:** Store in a cool, dry place in original container. Do not use or store near heat or open flames. Protect product from direct sunlight.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinse water 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:

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment, and then dispose of liner in a sanitary landfill or by incineration if allowed by State and Locat authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

Clean up spills immediately. Cover the pesticide powder with absorbent material, such as dry sand, sawdust or earth. Collect spill by sweeping or shoveling into an appropriate waste disposal container. Dispose of waste in a manner approved by Local authorities. Avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

#### 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. 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.

PPD 06/03

