



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:

43813-35

Date of Issuance:

June 6, 2006

Term of Issuance:

Conditional

Name of Pesticide Product:

Bethoguard™ 300 SC

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(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. 43813-35".

Signature of Approving Official:

Adam Heyward
Product Manager Team-34
Regulatory Management Branch II
Antimicrobials Division (7510C)

Date:

June 6, 2006

- 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."

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)

Janssen Pharmaceutica

BETHOGUARD™ 300 SC

Biocide For Industrial Use in Material Preservation

ACTIVE INGREDIENT: (w/w)

BETHOXAZIN:

3-(Benzo[b]thiophen-2yl)-5,6-dihydro-1,4,2-oxathiazine, 4-oxide.....31.1%

INERT INGREDIENTS: (w/w).....68.9%

TOTAL100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

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, or 1-800-424-9300 immediately 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, or 1-800-424-9300 immediately for treatment advice.
IF SWALLOWED	Call a poison control center, or doctor, or 1-800-424-9300 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 the 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, or 1-800-424-9300 immediately for treatment advice.
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.	

SEE OTHER PANEL FOR PRECAUTIONARY STATEMENTS

NET CONTENTS: 52.8 gallons (200 liters)

EPA REG. NO. 43813-XX

EPA EST. NO. 074263-DEU-001



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. 43813-35

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

DANGER

Corrosive. Causes irreversible eye damage. Do not get in eyes, on skin or on clothing. Harmful if swallowed or inhaled. Avoid breathing spray mist. **Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.**

HANDLER PERSONAL PROTECTIVE EQUIPMENT

- When mixing, loading, or applying pesticide, and for routine cleaning or maintenance of equipment, wear protective eyewear (goggles, face shield or safety glasses), protective clothing (long sleeved shirt, long pants, socks, and safety shoes), chemical resistant gloves such as natural rubber, polyethylene or PVC and a respirator with an organic-vapor removing cartridge with a pre-filter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P, or HE pre-filter.
- Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

PESTICIDE USER SAFETY REQUIREMENTS:

- Discard clothing and other absorbent materials that have been heavily contaminated with this product. Do not reuse them.
- 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.

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.

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.

PHYSICAL OR CHEMICAL HAZARDS:

With settling, BETHOGUARD 300 SC may develop a concentration gradient from the top to the bottom of the container, eventually resulting in the appearance of a clear liquid on the top. Prior to use or sampling, homogenize the formulation thoroughly. For small containers, secure the cap and vigorously agitate by inverting the closed container several times. For larger containers, mix BETHOGUARD 300 SC thoroughly by using a power stirrer or drill at slow speed.

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DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Bethoguard 300 SC is to be incorporated into the following materials at suitable stages of the manufacturing process to preserve the integrity of the manufactured/treated materials. **Not for use in food grade paper, paperboard, paper coatings and adhesives.**
Not for use in textiles used for clothing articles.

TYPES OF MATERIALS:

Textiles & Fibers/Fabrics (including multi-fiber blends and synthetic blends with natural fibers) such as: acetate, acrylic, cotton, nylon, polyester, polyethylene, polypropylene, polyvinylchloride, rayon, wool, and coating/finishes applied to such materials.

Building Materials including adhesives, caulks, grouts, gel coats, glazing compounds, sealants, patching compounds, dry wall, gypsum, perlite, plaster-like or mineral based materials, paper & paperboard (non-food contact).

APPLICATIONS

Manufactured materials may be used in the following end-use applications such that the finished product contains 0.10% to 1.0% by weight of the active ingredient:

Textiles & Fibers/Fabric: Tents, tarpaulins, awnings, shower curtains, curtains (window, shower, cubicle).

Building Materials (non-food contact): including adhesives, caulks (including tub & tile), grouts, gel coats, sealants, patching compounds, dry wall, gypsum, perlite, plaster-like or mineral based materials, paper & paperboard for insulation wallboard, and wall coverings, bathtubs and bathtub enclosures, flooring (concrete, epoxy, component fibers, vinyl, linoleum & coatings), handles & knobs, whirlpools, shower stalls, tile, ceiling tile, walls, wall coverings, partitions, toilets and toilet components/accessories.

Specific manufacturing directions for a given application will be provided by consultation with Janssen Pharmaceutica.

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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: Triple rinse container. Then offer for recycling or reconditioning or puncture and dispose of using one of the following methods: (1) deposit metal or plastic containers in a sanitary landfill, (2) incinerate or burn, if allowed by state and local authorities, plastic containers. If burned, stay out of smoke.

Clean up spills immediately. Contain and absorb spills with inert material such as sand, calcium carbonate, clay or sawdust. Collect absorbed material by sweeping or shoveling into an appropriate waste disposal container. Wash spill area with water and absorb wash water in the same manner. Do not contaminate waterways. 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.

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