

43813-30

07-28-2006

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

August 11, 2006

William R. Goodwine
Senior Director
Janssen Pharmaceutica
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Subject: XAMOX 30L
EPA Registration No.: 43813-30
Application Date: June 28, 2006
Receipt Date: July 28, 2006

Dear Mr. Goodwine,

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- Addition of the phrase "or equivalent treating methods giving comparable retentions" in treatment section of directions for use.

General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422.

Sincerely,

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES							
INBOL	7510P						
JRNAME	Grain						
DATE	8/11/06						



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Janssen Pharmaceutica/43813-30		2. EPA Product Manager ADAM HEYWARD		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Janssen Pharmaceutica/XAMOX 30L Wood Preservative		PM# 34			
5. Name and Address of Applicant (Include ZIP Code) Janssen Pharmaceutica 1125 Trenton-Harbourton Road Titusville, NJ 08560-0200 <input type="checkbox"/> Check if this is a new address			6. Expedited Review: In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____		

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me-Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label Change: Include the phrase "or equivalent treating methods giving comparable retentions" in treatment section of directions to use. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container	
2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____			3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		
4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>			
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name William R. Goodwine		Title Sr. Director		Telephone No. (Include Area Code) (609) 730-2607	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.					8. Date Application Received (Stamped)
2. Signature 			3. Title Sr. Director		
4. Typed Name William R. Goodwine			5. Date JUNE 28, 2006		

JANSSEN



PHARMACEUTICA INC.

June 28, 2006

Document Processing Desk (NOTIF)
Office of Pesticide programs (7504P)
U.S. Environmental Protection Agency
Room S - 4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

AD

RE: XAMOX 3OL (43813-30)
Notification per PRN 98-10 - Label change to directions for use

ATTN: Mr. Adam Heyward
Product Manager 34

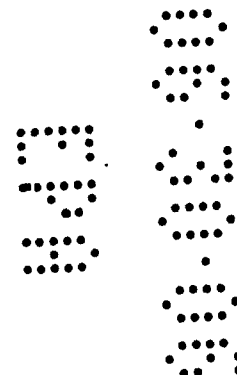
Janssen requests that the phrase "or equivalent treating methods giving comparable retentions" be added to the treatment section of the XAMOX 3OL wood preservative label by notification per PRN 98-10 (M) (3).

Addition of the phrase "or equivalent treating methods giving comparable retentions" would allow other pressure treating processes not specifically mentioned on the label as well as diffusion (non-pressure) treatments that give comparable retention levels. Referring to EPA Memorandum dated 18 April 2006 on Human Risk Assessment which assessed both pressure and non-pressure application scenarios, it is clear that the proposed label revision would result in no greater exposure than methods currently cited on the label. Secondly, there are no proposed changes to the dosage, concentration, timing, or frequency of product application. Finally the product is not registered for public health or as a termiticide (interpreted to mean intended for pretreatment for structural protection based on the recent determination by RD Efficacy Team that XAMOX claims are for wood preservation as treated article and not the former).

Enclosed are 5 copies of the revised XAMOX 3OL labeling with the proposed revisions highlighted. Please contact me if you should have any questions.

Sincerely,

William R. Goodwine
Senior Director
Tel: (609) 730-2607 Fax: (609) 730-3138
bgoodwi@janus.jnj.com



PLANT & MATERIAL PROTECTION DIVISION
1125 TRENTON-HARBOURTON ROAD
TITUSVILLE, NEW JERSEY 08560-0200

Janssen Pharmaceutica

XAMOX™ 30L

INSECTICIDE AND FUNGICIDE WOOD PRESERVATIVE FOR INDUSTRIAL USE

Protects wood & wood products from termites, wood boring insects, and fungal decay.
For above ground use only. This product is not intended for use as a termite pretreatment for structural protection.

NOTIFICATION
Date Reviewed: 08-11-04
Reviewed By: A. E. ...

ACTIVE INGREDIENT: (w/w)
CYPROCONAZOLE:
2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazole-1-yl)
butan-2-ol 2.44%

THIAMETHOXAM:
4H-1,3,5-Oxadiazin-4-imine,3-[(2-Chloro-5-thiazolyl)
methyl]tetrahydro-5-methyl-N-nitro 0.49%

INERT INGREDIENTS: (w/w) 97.07%
TOTAL 100.00%

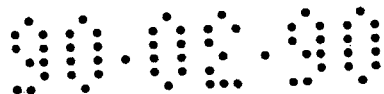
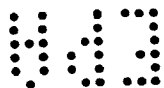
Contains 0.22 lbs. Cyproconazole and 0.04 lbs Thiamethoxam per gallon

KEEP OUT OF REACH OF CHILDREN

WARNING

NET CONTENTS: 55 gallons (208 liters)

EPA REG. NO. 43813-30
EPA EST. NO. 43813-BL-2



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

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

WARNING

Causes substantial but temporary eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses) and impervious gloves when handling. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Applicators and other handlers must wear:

- Coveralls over long-sleeved shirt and long pants,
- Socks and chemical-resistant footwear,
- Goggles or face shield and,
- Chemical resistant gloves (such as barrier laminate or butyl nitrile/neoprene rubber, PVC, viton at ≥ 14 mils).

USER SAFETY RECOMMENDATIONS

- Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users must remove personal protective equipment (PPE) immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

STATEMENT OF PRACTICAL TREATMENT

FIRST AID	
IF IN EYES	<ul style="list-style-type: none">• Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes.• Remove contact lenses, if present, after the first 5 minutes. Then continue rinsing eye.• Call a poison control center or doctor for further treatment advice.
IF ON SKIN	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 - 20 minutes.• Call a poison control center or doctor for further treatment advice
IF SWALLOWED	<ul style="list-style-type: none">• Call a poison control center or doctor for further 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	<ul style="list-style-type: none">• Remove person to fresh air.• If not breathing, give artificial respiration, preferably mouth-to-mouth, if possible.• Get medical attention
HOT LINE NUMBER	
For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents) call the National Pesticide Telecommunications Network at 1-800-858-7378. For chemical emergency assistance (spill, leak, fire, or accident), call Chem Trec at 1-800-424-9300.	
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.	

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with it's labeling.

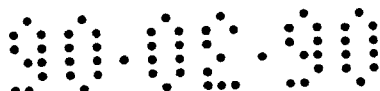
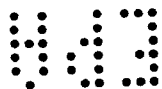
Description: XAMOX 30L is a wood preservative concentrate that requires dilution with SOLTROL™ 130H or other similar aliphatic mineral spirit prior to use on wood products to protect against decay (brown and white rot), termites and wood boring insects.

Product Uses: Only for pressure treatment application to millwork components for window and door manufacture, dimensional softwood lumber for structural uses (such as framing, studs, joists, sill & floor plates), structural panels (such as plywood and oriented strand board) and structural engineered wood (such as I-joists, glulam beams, laminated veneer lumber, parallel & oriented strand lumber) that are used in above ground applications and protected from weathering. Do not use on wood that will come in contact with food.

Wood Preparation: Machine, cut, glue, and sand wood as desired before treating. Wood should be kiln dried or air seasoned to a moisture content, of about 25% or less, that will permit adequate penetration of preservative during treatment.

Treatment: For control of decay, wood boring insects and termites, apply XAMOX 30L by pressure treatment processes (such as double vacuum, full-cell or modified full-cell) or equivalent treating methods giving comparable retentions. Pressure treatment should be performed according to the typical methods described in the American Wood Preservers' Association (AWPA) Standards. Target retention levels for cyproconazole and thiamethoxam in the treated wood products are 0.05-0.2 kg/m³ for cyproconazole and 0.01-0.04 kg/m³ for thiamethoxam. These retentions are achieved with an uptake of 2 - 8 fluid ounces of XAMOX 30L in a maximum of 2 gallons of treating solution per cubic foot of wood. All treated wood must be held on the drip pad until drippage has stopped. Treated wood should be stored in a weather-protected environment with adequate ventilation for dissipation of solvent vapors.

Finishing: Before glazing, staining, painting, varnishing, or application of water repellents, treated wood should be completely dry and odor-free. Pressure treated wood requires drying after treatment to a moisture content suitable for the type of coating to be applied.



ENVIRONMENTAL HAZARDS:

This product is toxic to wildlife and highly toxic to aquatic invertebrates. Do not apply directly to water, or to areas where water is present, or to inter-tidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash water. 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.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in original container in a cool, dry place.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. 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 container then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or by other procedures approved by State and Local authorities.

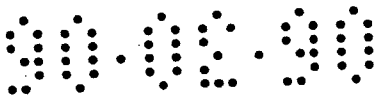
NOTICE OF WARRANTY

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. To the extent permitted by law, Janssen Pharmaceutica disclaims any liability 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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*Thiamethoxam is manufactured by Syngenta Crop Protection AG, Basel, Switzerland

PPD 05/06



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