

43813-30

10-16-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OCT 16 2009

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

William R. Goodwine  
Janssen PMP, a Division of Janssen Pharmaceutica  
1125 Trenton-Harbourton Road  
Titusville, NJ 08560-0200

Subject: **XAMOX 30L**  
EPA Registration No.: 43813-30  
Application Date: September 14, 2009  
Receipt Date: September 16, 2009

Dear Mr. Goodwine:

This acknowledges receipt of the notification identified above submitted under the provision section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10.

**Proposed Notification:**

Revised Precautionary Statements:

- Update Container Language as per PR Notice 2007-4

**General Comment:**

A copy of this accepted notification has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, you may contact Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at [grigsby.stacey@epa.gov](mailto:grigsby.stacey@epa.gov) during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

ShaRon Carlisle  
(Acting) Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
	<b>Application for Pesticide - Section I</b>		

<b>1. Company/Product Number:</b> 43813-30	<b>2. EPA Product Manager:</b> ShaRon Carlisle	<b>3. Proposed Classification</b> <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
<b>4. Company/Product (Name)</b> XAMOX 30L	<b>PM#</b> 34	
<b>5. Name and Address of Applicant (Include ZIP Code)</b> Janssen PMP, a Division of Janssen Pharmaceutica, N.V. 1125 Trenton-Harbourton Road Titusville, NJ 08560-0200  <input type="checkbox"/> Check if this is a new address		<b>6. Expedited Review.</b> 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.)

"Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156, 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**

<b>1. Material This Product Will Be Packaged In:</b>				<b>2. Type of Container</b>	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
* Certification must be submitted		If "Yes" Unit Packaging wgt.    No. per container	If "Yes" Package wgt    No. per container	Metal Plastic Glass Paper Other (Specify) <u>HDPE</u>	
<b>3. Location of Net Contents Information</b>		<b>4. Size(s) Retail Container</b>		<b>5. Location of Label Directions</b>	
<input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		52.8 & 264 Gallons (200 & 1000 L)		<input type="checkbox"/> On Label	
<b>6. Manner in Which Label is Affixed to Product</b>			<input checked="" type="checkbox"/> Lithograph Paper glued 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.)**

<b>Name:</b> William R. Goodwine	<b>Title:</b> Senior Director, Regulatory Affairs & Product Development	<b>Telephone No. (Include Area Code)</b> (609) 730-2607
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<b>Certification</b> 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 or both under applicable law.	<b>6. Date Application Received</b> (Stamped)
<b>2. Signature:</b> 	<b>3. Title:</b> Senior Director, Regulatory Affairs & Product Development
<b>4. Typed Name:</b> William R. Goodwine	<b>5. Date:</b> September 14, 2009

# 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.

**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

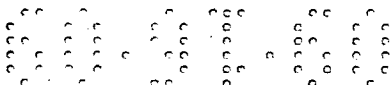
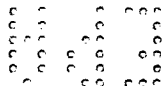
**KEEP OUT OF REACH OF CHILDREN**

**WARNING**

NET CONTENTS: 55 gallons (208 liters)

EPA REG. NO. 43813-30

EPA EST. NO. 43813-BL-2



**JANSSEN PMP**

a Division of Janssen Pharmaceutica NV  
1125 Trenton-Harbourton Rd.  
Titusville, NJ 08560-0200

NOTIFICATION  
Date Reviewed: 10/16/09  
Reviewed By: Tracey Grigby

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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  $\geq 14$  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**

<b>FIRST AID</b>	
<b>IF IN EYES</b>	<ul style="list-style-type: none"> <li>• Hold eyelids open and flush with a steady, gentle stream of water for 15 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 for further treatment advice.</li> </ul>
<b>IF ON SKIN</b>	<ul style="list-style-type: none"> <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 for further treatment advice.</li> </ul>
<b>IF SWALLOWED</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor for further 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>
<b>IF INHALED</b>	<ul style="list-style-type: none"> <li>• Remove person to fresh air.</li> <li>• If not breathing, give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>• Get medical attention.</li> </ul>
<b>HOT LINE NUMBER</b>	
<p>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.</p>	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
<p>Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

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

**Description:** XAMOX 3OL 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 3OL 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/m<sup>3</sup> for cyproconazole and 0.01-0.04 kg/m<sup>3</sup> for thiamethoxam. These retentions are achieved with an uptake of 2 – 8 fluid ounces of XAMOX 3OL 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.

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**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 HANDLING:**

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows:

[For containers > 5 gallons in size] - Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

**NOTICE OF WARRANTY**

Janssen PMP, a Division of Janssen Pharmaceutica NV 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 PMP. To the extent permitted by law, Janssen PMP disclaims any liability for consequential, special or indirect damages resulting from the use, handling, application, storage or disposal of this product or for damages in the nature of penalties, and the buyer and user waive any right that they may have to such damages. **To the extent consistent with applicable law, Janssen PMP makes no warranties of merchantability or of fitness for a particular purpose or any other express or implied warranty except as stated above.**

<sup>TM</sup>Trademark of Janssen Pharmaceutica.

\*Thiamethoxam is manufactured by Syngenta Crop Protection AG, Basel, Switzerland

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