

43813-31

10-16-2009

1/5

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 10TK**
EPA Registration No.: 43813-31
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 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

CONCURRENCE Microbials Division (7510P)

SYMBOL							
SURNAME							
DATE							



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 43813-31	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) XAMOX 10 TK	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) 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		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.)

"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

1. Material This Product Will Be Packaged In:				2. Type of Container	
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	If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) HDPE
* Certification must be submitted		If "Yes" Package wgt.	No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 52.8 & 264 Gallons (200 & 1000 L)		5. Location of Label Directions <input type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product			<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.)			
Name William R. Goodwine	Title Senior Director, Regulatory Affairs & Product Development	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 or both under applicable law.			6. Date Application Received (Stamped)
2. Signature <i>William R. Goodwine</i>	3. Title Senior Director, Regulatory Affairs & Product Development		
4. Typed Name William R. Goodwine	5. Date September 14, 2009		

XAMOX™ 10TK

Insecticide For Manufacturing Purposes Only
For use in formulating industrial wood preservative products

ACTIVE INGREDIENT: (w/w)

THIAMETHOXAM:

4H-1,3,5-Oxadiazin-4-imine,3-[(2-Chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro 9.9%

INERT INGREDIENTS: (w/w) 90.1%

TOTAL 100.0%

Contains 0.97 lbs. active ingredient/gallon

NOTIFICATION

Date Reviewed: 10/16/09

Reviewed By: *[Signature]*

KEEP OUT OF REACH OF CHILDREN

DANGER

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 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 ON SKIN OR CLOTHING	<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 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 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: Treat symptomatically.	

NET CONTENTS: 55 gallons (208 liters)

EPA REG. NO. 43813-31

EPA EST. NO. 43813-BL-2

JANSSEN PMP

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

y/w

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

DANGER

CORROSIVE: Causes irreversible eye damage. Do not get in eyes, on skin or clothing. Harmful if swallowed or absorbed through skin. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long sleeved shirt and long pants
- Socks and shoes
- Chemical-resistant gloves (such as: Barrier Lamine, or any of the following gloves at ≥ 14 mils thickness: butyl nitrile, neoprene rubber, polyvinyl chloride, or Viton).
- Goggles, face shield or safety glasses

USER SAFETY RECOMMENDATIONS

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should 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
SURFACE WATER ADVISORY**

This product may contaminate water through drift of spray in wind. This product has a high potential for run off for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce run off that contains this product. A level, well maintained vegetative buffer strip between treating areas and surface water features such as ponds, streams and springs will reduce the potential for contamination of water from rainfall runoff (See manual at the following internet address: <http://www.nrcus.usda.gov/water/quality/common/pestmgt/files/core4.html>)

Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

GROUND WATER ADVISORY

Thiamethoxam has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

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.

4/17

DIRECTIONS FOR USE:

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

GENERAL INFORMATION: XAMOX 10TK is an insecticide to be used for the formulation of wood protection end use products that have a U.S. EPA registration

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 may be toxic. 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 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 or reconditioning or puncture and dispose of using one of the following methods: (1) depositing in a sanitary landfill, (2) incineration, or (3) burning, if allowed by state and local ordinances. Stay out of smoke from burning containers.

For minor spills, leaks, etc. follow all precautions indicated on this label and clean up immediately.

Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes. In the event of a major spill, fire, or other emergency, call 1-800-424-9300, day or night.

PHYSICAL OR CHEMICAL HAZARDS: Do not use, pour, spill or store near heat or open flame.

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.**

7/15