

43813-29

12/31/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Janssen UMP,
a Division of Janssen Pharmaceutia, N.V.
1125 Trenton-Harbourton Road
Titusvill, NJ
08560

DEC 31 2010

Attention: William R. Goodwine

Subject: XAMOX Technical
EPA Registration No: 43813-29
Notification Dated November 29, 2010

This will acknowledge receipt of your Notification to update the container handling statement per PR Notice 2007-4 and make other minor changes to the product label, submitted under the provision of FIFRA Section 3(c)(9).

Proposed Notification:

Revise label per PR Notice 2007-4 and additional minor label changes

General Comments:

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

The Notification dated November 29, 2010 is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file

If you have any questions concerning this letter, please contact Zebora Johnson at (703) 308-7080.

Sincerely

Marshall Swindell
Product Manger (33)
Regulatory Management Branch I
Antimicrobial's Division (7501P)



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 43813-29 | 2. EPA Product Manager Marshall Swindell | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) XAMOX TECHNICAL | PM# 33 | |
| 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 | | <input type="checkbox"/> Metal | <input type="checkbox"/> Plastic |
| * Certification must be submitted | | | | <input type="checkbox"/> Glass | <input type="checkbox"/> Paper |
| If "Yes" Unit Packaging wgt. | No. per container | If "Yes" Package wgt | No. per container | xxxxxx Other (Specify) <u>Fiber Drum</u> | |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container 132 lbs. (60 kg) | | 5. Location of Label Directions <input type="checkbox"/> on label | |
| 6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | | | <input type="checkbox"/> Other _____ | |

Section - IV

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| 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, both under applicable law. | | 6. Date Application Received (Stamped) |
| 2. Signature <i>William R. Goodwine</i> | 3. Title Director, WW Regulatory Affairs & Product Development | |
| 4. Typed Name William R. Goodwine | 5. Date November 29, 2010 | |

Janssen Pharmaceutica

XAMOX™ TECHNICAL

Insecticide For Manufacturing Purposes Only

For use in formulating industrial
wood preservative products

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ACTIVE INGREDIENT: (w/w)

THIAMETHOXAM:
4H-1,3,5-Oxadiazin-4-imine,3-[(2-Chloro-
5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro 98.0%

INERT INGREDIENTS: (w/w) 2.0%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side panel for additional precautionary statements

NET CONTENTS: 132 pounds (60 kilograms)

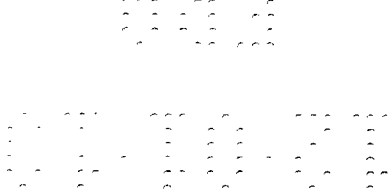
EPA REG. NO. 43813-29
EPA EST. NO. 43813-BL-2



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

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



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

CAUTION

Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes or clothing.
Wash thoroughly with soap and water after handling.

STATEMENT OF PRACTICAL TREATMENT

| FIRST AID | |
|--|---|
| IF INHALED | <ul style="list-style-type: none"> • Move the person to fresh air. • If person is not breathing, call 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. |
| IF IN EYES | <ul style="list-style-type: none"> • 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 | <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, or 1-800-424-9300 immediately for treatment advice. |
| IF SWALLOWED | <ul style="list-style-type: none"> • 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. |
| 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: If ingested, induce emesis or lavage stomach. Treat symptomatically. | |

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| USER SAFETY RECOMMENDATIONS Users should: <ul style="list-style-type: none"> • 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. |
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**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/pestmgmt/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.

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