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

MAR - 2 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

William R. Goodwine
Sr. Director, Regulatory Affairs & Product Development
Janssen PMP, a Division of Janssen Pharmaceutica NV
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Subject: **XAMOX® 100 SL**
EPA Registration Number: 43813-36
Application Date: January 22, 2009
Receipt Date: January 22, 2009

Dear Mr. Goodwine:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide (FIFRA), as amended, is acceptable with conditions.

Proposed Amendment

- New Use; Non-Food; Other Uses; Indoor

Conditions

Revise the label as follows:

1.) PRN 2005-1, Guidance for Mandatory and Advisory Labeling Statements, states that: **"Mandatory statements**, which commonly use imperative verbs such as "must" or "shall", either require action or prohibit the user from taking certain action. **Advisory statements** generally provide information, either in support of the mandatory statements or about the product in general. **To ensure that the intent of each labeling statement is clear, mandatory statements need to be clearly distinguishable from advisory statements."**

Therefore, you must revise the "Directions for Use" and "Precautionary Statement" by deleting the terms, "should" and replace with "must". Also, delete subheading "User Safety Recommendations" as the text in this section falls under User Safety Instructions.

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2.) Revise the first statement under "Environmental Hazards" to read:

"This pesticide is highly toxic to beneficial terrestrial insects, including honey bees, and to aquatic insects." Also delete the second statement in this section because it does not apply to how this product is used.

3.) The following statement must be added to your product label:

"This wood preservative product provides supplemental structural protection of wood and is not intended to be a stand-alone substitute for pre-construction or post-construction soil treatment/barrier termiticide application, with products registered for structural protection. When wood treated with this product is used for new construction, in the absence of a termiticide application registered for full structural protection, an annual re-inspection by a pest control/termiticide application registered for full structural protection, an annual re-inspection by a pest control/termiticide applicator licensed by the state is required. For structures where a soil treatment/barrier termiticide has been applied and/or a termite bait system installed, wood treated with this product may be used as an additional protection from subterranean termites that may have penetrated the chemical gaps occurring within the termiticide-treated soil or have bypassed the bait/monitor systems."

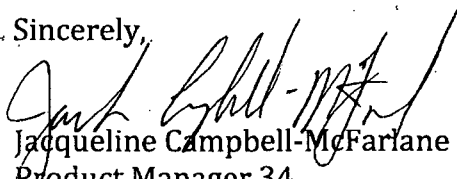
4.) Add the statement,

"Wood treated with Xamox 100 SL must not be used in bees hives or apiaries", to the Directions for Use.

General Comments

A stamped label with conditions is enclosed for your records. Submit a copy of your final printed label before distributing or selling the product bearing the revised labeling.

If you have further questions concerning this letter, then please contact me by telephone at (703) 303-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 308-6440 or by email at grigsby.stacey@epa.gov. When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,

Jacqueline Campbell-McFarlane
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: stamped label

CONCURRENCES

SYMBOL				2			
SURNAME							
DATE							

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XAMOX™ 100 SL**INSECTICIDE WOOD PRESERVATIVE FOR INDUSTRIAL USE**

Protects wood & wood products from termites and wood boring insects.

For above ground use only.

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR - 2 2011

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 43813-36**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	
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: Treat symptomatically.	

NET CONTENTS: 55 gallons (208 liters)

EPA REG. NO. 43813-36

EPA EST. NO. 43813-BL-2

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

PRECAUTIONARY STATEMENT 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 Laminate, 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

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.

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 DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple-rinse container (or equivalent) promptly after emptying. Triple-rinse as follows: Empty the remaining contents into application equipment or a mix-tank. Fill the container $\frac{1}{4}$ 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 reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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.

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

Description: XAMOX 100 SL is a wood preservative concentrate that requires dilution with water or mineral spirits prior to use on wood products to protect against 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 wood boring insects and termites, apply XAMOX 100 SL 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 thiamethoxam in the treated wood products are 0.01-0.04 kg/m³. These retentions are achieved with an uptake of 0.1 – 0.4 fluid ounces of XAMOX 100 SL 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.

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 or handling of this product. All such risks shall be assumed by the Buyer. JANSSEN PMP MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.