

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

COPY

MAY - 3 2010

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

William R. Goodwine
Janssen Pharmaceutica NV.
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Subject: **WOCOSEN™**
EPA Registration No. 43813-16
Application Date: April 30, 2009
Receipt Date: May 1, 2009

Dear Mr. Goodwine:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3 (c) 7 A as amended, is acceptable with conditions.

Proposed Amendment:

- Increase in rates for Paints and Stains

Data Summary

Data Requirement	Means of Support	Status
Dermal Penetration Study (in vivo)	Submitted study, MRID 477365-03	Acceptable, Dermal Absorption Factor 1% and 26.6% for 10 hour exposure for paints and stains only.

The Occupational and Residential Exposure Assessment identified the following risks:

The calculated maximum rate of exposure (MOE) for the short-term dermal exposure for the professional applicator applying stain using an airless sprayer is below the target MOE of 100 (MOE=52) and is at a level of concern.

The calculated MOE for the short-term dermal exposure for the homeowner applicator applying stain using an airless sprayer is below the target MOE of 100 (MOE=80) and is a level of concern.

However, the restrictive statements "do not use airless sprayer" and "apply wood preservative or wood preservative stain by brush, roller or low pressure hand wand (LPHW)", must be added to the "Penetrating Wood Preservatives and Wood Preservative Stains" directions to mitigate the risks outlined above.

CONCURRENCES

SYMBOL	SURNAME	DATE

Conditions:

Revise the label as follows:

Revise the "Penetrating Wood Preservatives and Wood Preservative Stains" directions on page 8 by adding the statement "do not use airless sprayer to apply wood preservative or wood preservative stain."

General Comments

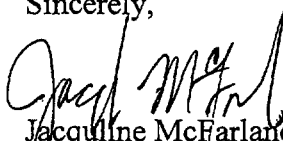
A stamped label with conditions is enclosed. Submit a copy of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by email at grigsby.stacey@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



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

CONCURRENCES

SYMBOL							
URNAME							
DATE							

Recommendation of Division Directors
Negotiated Due Dates

Decision#: 409437 Registration#: 43813-16 Petition #:

Fee Category: A500.0 PRIA Decision Time Frame: 60 days

Submitted by: Jacqueline McFarlane/ Stacey Grigsby Branch: RMB II Date: 3/1/10

Company: Janssen Preservation and Material Protection

Original Due Date: 3/1/10 Proposed New Due Date: 5/1/10

Previous Negotiated Due Dates: N/A

Is the "Fix" in-house? Yes. If not, date "Fix" expected:

Issue (describe in detail):
Background: Janssen has submitted a new use for the active ingredient propiconazole. The ecological and occupational risk assessment identified risks to the environment and workers.
Issues External: Company has to modify label to address the eco and occupational risks.
Issue Internal: Initially, the aggregate risk was not calculated because there were no dietary risk exposures. However, this active is used on agricultural crops, an aggregate review will be necessary in potentially modifying reduced rates and address exposure concerns of the application process of the worker in support of this registration.

Summary of Deficiency Type(s): Not Submitted (N) Deficiencies (D)
Product Chemistry: ___ **Acute Tox:** ___ **Efficacy:** ___ **Labeling:** ___ **Other (describe):** ___

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The company was email the risk assessments. Since they are working w/ Syngenta to add the use to their label, the registrant had to confer with Syngenta representatives before agreeing to renegotiate the due date. The company is not in agreement with the Agency's exposure risk assessment, therefore a meeting has been scheduled to discuss their concerns. The company is in agreement with the need of an extension and understands the Agency's concerns. The company is working with Syngenta to address the eco concerns. However, they agreed to the 60 day extension.
Recommendation: PRIA due date needs to be renegotiated an additional 60 days to allow the Agency adequate time to make a determination on the aggregate risk.

"75 Day" Letter sent? _____ (Date sent) Yes X No and reason for none?
 Agency policy decision

Rationale for Proposed Due Date:
 PRIA due date needs to be renegotiated an additional 60 days to allow the Agency adequate time to make a determination on the exposure concerns and to modify reduced rates.

Registrant notified that this is the last negotiation? Yes X Not Applicable

Approve: [Signature] 3-1-10 Disapprove:

If disapproved, action to be taken			CONCURRENCES			
SYMBOL	7510P	7510P	7510P			
SIGNATURE	[Signature]	[Signature]	[Signature]			
DATE	3/1/10	3/1/10	3/1/10			

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

CAUTION

Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing spray mist. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT

Handlers must wear: Long sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves (such as barrier laminate, or any of the following gloves at \geq 14 mils thickness: butyl nitrile, neoprene rubber, polyvinyl chloride or viton).

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. 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 authorities are 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 the 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

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

[For containers \leq 5 gallons in size] – Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[For containers $>$ 5 gallons in size] - 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 puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

TMTrademark of Janssen PMP.

*Propiconazole is manufactured by Syngenta, Basel, Switzerland

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WOCOSENTM 250EC

Preservative for Industrial & Commercial Use

ACTIVE INGREDIENT: (w/w)

PROPICONAZOLE*:

1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole 23.6%

OTHER INGREDIENTS: (w/w) 76.4%

TOTAL 100.0%

Product weight: 8.85 lbs./gal. (1.06 kg/L)

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If swallowed	-Call a poison control center or doctor 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 a poison control center or doctor. -Do not give anything by mouth to an unconscious person.
If in eyes	-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 for treatment advice.
If on skin or clothing	-Take off contaminated clothing. -Rinse skin immediately with plenty of water for 15-20 minutes. -Call a poison control center or doctor for treatment advice.
If inhaled	-Move person to fresh air. -If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. -Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER: Chem Trec: (800) 424-9300 Have the product container with you when calling a poison control center or doctor, or going for treatment	
NOTE TO PHYSICIAN There is no specific antidote for Wocosen 250EC. Give a saline laxative and supportive therapy.	

NET CONTENTS: 52.8 gallons (200 liters)

EPA REG. NO. 43813-16

EPA EST. NO.

JANSSEN PMP
a Division of Janssen Pharmaceutica NV
1125 Trenton-Harbourton Road
Titusville, NJ 08560

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

MAY - 3 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

43813-16

DIRECTIONS FOR USE

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

SAPSTAIN AND MOLD CONTROL:

Wocosen 250EC is used to control sapstain and mold in freshly cut hardwood and softwood lumber, poles, posts, timbers and other manufactured wood products. Examples of other wood products include:

Logs: Fungal staining can be inhibited in freshly debarked logs used for log home construction, export, yarding prior to sawing and other purposes.

Wood Furnish: Engineered wood composites, such as particle board, wafer board, oriented strand board, and similar products can be protected from fungal discoloration during storage by treatment with WOCOSEN 250EC.

Wood Chips/Saw Dust: Treatment of wood chips, saw dust or other similar by products intended for papermaking (Not for food grade/food contact paper or paper board) reduces fungal discoloration and lowers bleaching requirements for finished paper products.

Plywood Veneer: Treatment with WOCOSEN 250EC is effective for freshly peeled green veneer and other similar plywood furnish that can be especially subject to stain and mold development that can interfere with appearance or laminating adhesive performance.

Wocosen 250EC is applied by dipping or spraying the wood until complete surface wetting is achieved. For bulk dip tanks Wocosen 250EC is diluted by using 0.13 – 1 gallon of Wocosen 250EC in 100 gallons of water. Agitate vigorously until completely dispersed. For conventional spray systems a 0.25% to 2% Wocosen 250EC spray solution is used. For example, in a 100 gallon day tank, 0.25 to 2 gallons of Wocosen 250EC are added to the day tank and then enough water is added to bring the total volume up to 100 gallons of solution. In electrostatic spray applications, Wocosen 250 EC dilution is not required, treatment strength is varied by number of application nozzles used and line speed. Rates, for all applications used, will vary according to temperature, humidity, wood moisture, storage conditions, etc. Contact your local Wocosen 250EC product representative for application advice.

Remove sawdust and other debris from treating solution on a regular basis to maintain correct concentration of Wocosen 250EC in application solution. To prevent fungal attack below the surface of the wood, freshly sawn lumber should be treated within 24 hours.

For sapstain application, treated lumber must be stored under cover, indoors, or at least 100 feet from any pond, lake, stream, wetland, or river to prevent possible runoff of the product into the waterway. Treated lumber stored within 100 feet of a pond, lake, stream, wetland, or river must be either covered with plastic or surrounded by a berm to prevent surface water runoff into the nearby waterway. If a berm or curb is used around the site, it should consist of impermeable material (clay, asphalt, concrete) and be of sufficient height to prevent runoff during heavy rainfall events.

DECAY AND STAIN PROTECTION

Description: WOCOSEN 250EC is a wood preservative concentrate which requires dilution with water prior to use on wood products to protect against decay (brown and white rot) and staining fungi (blue stain).

Treated wood shall not be used in the construction of beehives.

Product Uses: For application to millwork, shingles & shakes, siding, plywood, and structural lumber & composites that are used in above ground applications only. Do not use on wood which will come in contact with food.

Wood Preparation: Machine, cut, glue, and sand wood as desired before treating. Do not use over previously finished or stained wood without stripping off old finish. Wood must be clean and dry before treatment. Wood for pressure treatment should be kiln dried or air seasoned to a

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moisture content, of about 25% or less, that will permit adequate penetration of preservative during treatment.

Treatment: Apply by immersion, roller coater, flood, spray, brush or pressure treatment processes (double vacuum, full-cell or modified full-cell). For non-pressure application methods, mix 2 to 4 gallons of Wocosen 250EC with water to achieve 100 gallons of treating solution at the concentration of 0.5 - 1% a.i., respectively. Wood products to be treated by the bundle-dipping process should be completely immersed for three (3) minutes. Individual wood pieces treated by immersion, roller-coater or flood shall be treated for not less than fifteen (15) seconds. Coverage for brush and spray application is approximately 150 square feet per gallon of treating solution, but varies by the species and condition of the wood. Pressure treatment should be performed according to the methods described in the American Wood Preservers' Association (AWPA) Standards. A minimum propiconazole retention level of 0.025 pounds per cubic foot (pcf) is recommended. All treated wood must be held on the drip pad until drippage has stopped. Any surface, cut after first treatment should be retreated using 1% a.i. concentration solution.

Finishing: Before glazing, staining, painting, varnishing, or application of water repellents, treated wood should be completely dry and odor-free. For non-pressure applications, allow 4-8 hours drying time under average temperature and humidity conditions; treated wood can be heat dried for plant production. Pressure treated wood requires drying after treatment to a moisture content suitable for the type of coating to be applied.

Clean-up: Use water to remove wet WOCOSEN 250EC wood preservative from all surfaces, brushes and rollers.

COOLING TOWER WOOD:

Use Wocosen 250EC to protect cooling tower wood against surface rot and internal or dry rot. Apply by spraying or painting a solution containing 0.5% to 1.1% Wocosen 250EC in water onto the clean wood surfaces. The amount applied should provide 0.23 to 0.46 pounds Wocosen 250EC per 1000 sq. ft. of wood surface. Surface rot can also be inhibited by a periodic shock dose of Wocosen 250EC to the recirculating cooling water at the tower basin or cold well. The dosage should provide 1.7 pounds of Wocosen 250EC per 1000 gal. of water and the bleedoff should be stopped for 4 to 6 hrs. after treatment. The shock treatment should be repeated every four months.

IN CONTAINER PRESERVATIVE USES FOR FILM-FORMING COATINGS AND BUILDING MATERIALS (INCLUDING CAULKS, SEALANTS, ADHESIVES & BINDERS)

WOCOSEN 250 EC provides control of fungi causing stain, odor, degradation of physical properties, and/or product degradation when used as an in container preservative at levels between 0.2 - 5.3% (0.05 – 1.25% propiconazole), based on the total weight of the coating, or building material, such as mastics, caulks, joint cements, sealants, spackling, patching compounds, grouts, adhesives or emulsions and slurries used in their manufacture. Sufficient mixing to ensure adequate dispersion is required. WOCOSEN 250 EC cannot be used in adhesives applied to food packaging.

IN CONTAINER PRESERVATIVE USES FOR PENETRATING (SOLVENT-BASED) STAINS

WOCOSEN 250 EC provides control of fungi causing discoloration, odor, degradation of physical properties, and/or product degradation when used as an in container preservative at levels between 0.2 – 1.6% (0.05 – 0.4% propiconazole), based on the total weight of the penetrating stain.

IN CONTAINER PRESERVATIVE FOR INK

WOCOSEN 250 EC provides control of fungi causing stain, odor, degradation of physical properties, and/or product degradation when used as an in container preservative at levels between 0.2 - 5.0% (0.05 - 1.20% propiconazole), based on the total weight of the ink.

DRY FILM PRESERVATIVE OF COATINGS AND BUILDING MATERIALS (INCLUDING CAULKS, SEALANTS, ADHESIVES & BINDERS)

WOCOSEN 250 EC provides control of mold and mildew fungi causing stain, odor, or film degradation when used as a dry film preservative at levels between 0.2 - 5.3% (0.05 - 1.25% propiconazole), based on the total weight of the coating, or building material, such as mastics, caulks, joint cements, sealants, spackling, patching compounds, grouts, and adhesives. Sufficient mixing to ensure adequate dispersion is required. WOCOSEN 250 EC cannot be used in adhesives applied to food packaging. Preserved coating can be applied by brush, roller, or airless sprayer.

PENETRATING WOOD PRESERVATIVES AND WOOD PRESERVATIVE STAINS

WOCOSEN 250 EC provides control of decay and stain fungi on wood treated at levels between 1.0 - 3.2% (0.25 - 0.8% propiconazole), based on the total weight of the wood preservative or wood preservative stain. Preserved stain can be applied by brush, roller or low pressure hand wand.

PAPER, WALLBOARD (DRY WALL AND GYPSUM BOARD) AND PAPERBOARD PRODUCTS

WOCOSEN 250 EC will inhibit fungal mold and mildew growth which causes discoloration, odor and degradation in paper, wallboard, and paperboard. Apply with thorough agitation.

WOCOSEN 250 EC can be added to the wet end of a paper machine at rates such that 0.1 to 2.5 pounds active ingredient are retained per ton of dry fiber. Alternately, application may be made at the size press, water box or dry end of the paper machine at rates such that 0.1 to 2.5 pounds of active ingredient are retained per ton of dry paper. Regardless of application method, the maximum rate of application shall be such that not more than 2.5 pounds active ingredient are retained per ton of dry paper. WOCOSEN 250 EC may be applied to the gypsum core of wallboard to inhibit the growth of fungi. Apply 0.05 to 0.6 pounds of active ingredient per 1000 pounds of formulation (i.e. wet slurry). WOCOSEN 250 EC cannot be applied to paper or paper products that come into contact with food.

CEILING TILES

To inhibit the growth of fungi in ceiling tiles and in mineral-based building materials used in the manufacture of ceilings, add 0.5 to 4.25 pounds of active ingredient per 1000 pounds of formulation (i.e., wet slurry). WOCOSEN 250 EC can be added at any time during the formulation procedure.

RUBBER AND PLASTIC PRODUCTS

WOCOSEN 250 EC will control mold and mildew on rubber and plastic products such as curtains, bath mats, and thermoplastic rubber. WOCOSEN 250 EC may be added at rates from 0.1 to 0.5% active ingredient by weight. The temperature stability of WOCOSEN 250 EC may be influenced by the choice of heat stabilizer and plasticizer in the formulation. Testing should be done to confirm compatibility of WOCOSEN 250 EC with specific rubber or plastic products.

METALWORKING FLUIDS:

Use Wocosen 250EC to inhibit fungal degradation of water based and water emulsifiable cutting fluids and coolants used in metalworking operations. Add Wocosen 250EC to the fluid concentrate or to the

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diluted metalworking fluid in an amount which will provide 50 to 700 ppm active ingredient in the diluted fluid.

TEXTILES:

For the control of odor and stain causing microorganisms in textiles of the following products: shower curtains, carpet backing, awnings, boat covers, canvas, cordage, tents, tarpaulins, and wall coverings.

Addition of up to 2000 ppm of this active ingredient (8470 ppm of product), based on weight of goods, can inhibit the growth of mold and mildew that cause stains, odors and product degradation in textiles, fabrics and fibers composed of acetate, acrylic, acrylonitrile butadiene styrene, natural fibers (cotton, paper, wool, etc.), nitrile copolymers, nylon, polyester, polyethylene, polypropylene, rayon, rubber (natural & synthetic), coatings/finishes composed of silicone, urethane or vinyl applied to such materials. The material should be added at an appropriate manufacturing step to ensure adequate mixing and complete, uniform coverage of the treated material. Product can be applied by dye incorporation, pad, exhaust, or spray application.

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.**