

43813-49

03/09/2009

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 43813-49

Date of Issuance: MAR 9 2009

Term of Issuance: Conditional

Name of Pesticide Product: Sodium PYRION 40% MP

NOTICE OF PESTICIDE:
[x] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

William R. Goodwine
Janseen Pharmaceutica Inc.
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(a) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
a. Revise the "EPA Registration Number to read, "EPA Reg. No. 43813-49".

Signature of Approving Official:

Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Handwritten signature of Marshall Swindell

Date:

MAR 9 2009

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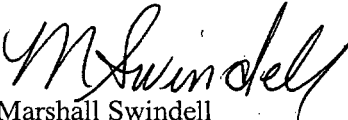
EPA Reg. No. 43813-48

- b. Insert a separate section for "**Pesticide Storage**". Insert the pertinent language in your labeling that should be inserted in that section (Do not store above 130° F (55° C). Keep container tightly closed when not in use. Do not store with strong oxidizing agents. Move the following language to the "**Pesticide Disposal**" section: "Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility".
- c. In the *Storage and Disposal* section, under the "**Pesticide Disposal**" statement, insert the following language (that is currently located in the "**Container Disposal**" section of this label): "Triple rinse as follows: 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 ¼ 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". These changes are required per the guidance from PR Notice 2007-4 (Labeling Revisions Required by the Final Rule" Pesticide Management and Disposal; Standards for Pesticide Containers and Containment).
- d. In the *Storage and Disposal* section, under the "Container Disposal" statement, the product must bear a batch code. This is a lot number of other code used by the registrant or producer to identify the batch of the pesticide product distributed and sold. This information is required per the guidance from PR Notice 2007-4.

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

A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

  
Marshall Swindell  
Product Manager Team-33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Enclosure: (Stamped Label)

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# SODIUM PYRION® 40% MP

## Manufacturing Use Product For Formulating Material Preservatives

Active Ingredient:  
 Sodium pyrithione (Sodium 2-pyridinethiol-1 -oxide) 40%  
 Inert Ingredients: 60%  
 Total: 100%

**KEEP OUT OF REACH OF CHILDREN**

### WARNING

FIRST AID	
<b>If in eyes</b>	-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.
<b>If swallowed</b>	-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.
<b>If on skin or clothing</b>	-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.
<b>If inhaled</b>	-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.
<p><b>HOT LINE NUMBER:</b></p> <p>For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents) call the National Pesticide Telecommunications Information Center 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><b>NOTE TO PHYSICIAN</b></p> <p>Convulsions, if persistent, may be controlled by careful intravenous use of short-acting barbiturates. Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

Net Wt:

EPA Reg. No.: 43813-

EPA Est. No.:

Manufactured for:

JANSSEN PMP

MAR 09 2009

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

Under the Federal  
Pesticide Act  
and the  
Federal Insecticide,  
Fungicide, and  
Rodenticide Act

# PRECAUTIONARY STATEMENTS:

## HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### WARNING

May be fatal if absorbed through skin or inhaled. Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Remove contaminated clothing and wash clothing before reuse.

ACCEPTED  
WITH COMMENTS  
In EPA Letter Dated:

MAR 09 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act, registered...

### PERSONAL PROTECTIVE EQUIPMENT [PPE]

Applicators and other handlers must wear: goggles or face shield, long sleeved shirt and long pants, socks and shoes, chemical-resistant gloves (such as rubber or waterproof gloves).

### USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

### USER SAFETY RECOMMENDATIONS

Users should 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. Remove PPE immediately after handling this product. Wash the outside of gloves before removing.

### ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, ponds, streams, estuaries, oceans or public 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 our State Water Board or Regional Office of the EPA. This pesticide is a chelating agent and should not be used with other chelating agents or with chlorine.

### CHEMICAL HAZARDS

Do not store or mix with strong oxidizing agents

**STORAGE AND DISPOSAL:** Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE** ~~WARNING~~ Do not store above 130°F (55°C). Keep container tightly closed when not in use. Do not store with strong oxidizing agents. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. 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 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. Offer for recycling if available or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Move this to section 10  
pesticide disposal

Move to Pesticide Disposal section

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**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not use for applications involving direct or indirect food/drinking water contact unless the end-use product is specifically approved for such use.

Only for the formulation of material preservative products for use in:

- ✓ Aqueous based fluids (metalworking, cutting, cooling & lubricating fluids)
- ✓ Metalworking, cutting, cooling & lubricating fluid concentrates
- ✓ Latex emulsions used in adhesives, caulks, patching compounds, sealants, pastes, & grouts
- ✓ Aqueous synthetic fiber lubricating (spin finishes)
- ✓ Aqueous based inks
- ✓ Natural and synthetic adhesives, latexes, urethane foams, caulks, patching compounds, sealants, architectural paints, industrial paints & coatings (including wood coatings), pastes, and grouts
- Laundry rinse additives & detergents, and carpet, surface, & floor cleaners
- Aqueous based chemical or mineral *Add Mixtures* used in concrete
- Aqueous analytical & diagnostic reagents
- Carrageenan based gels used to produce air fresheners
- Leather preservation
- Gypsum wallboard & dry wall; Gypsum, perlite, plaster-like, mineral based or cellulose derived building materials used in the manufacture of ceilings, ceiling tiles, walls & partitions.

Formulators using this product are responsible for obtaining EPA registration of their formulated product.

**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.**

®PYRION is a registered trademark of Janssen Pharmaceutica NV

PMP 10/08

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAR 09 2009

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