

43813-47

6/11/2008

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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:
43813-47

Date of Issuance:
JUN 11 2008

Term of Issuance:

Conditional

Name of Pesticide Product:
Zinc PYRION Powder MP

NOTICE OF PESTICIDE:
 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. 43813-47".

Signature of Approving Official:

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

Date:

JUN 11 2008

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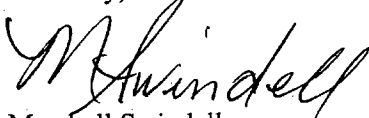
EPA Reg. No. 43813-47

- b. EPA's Label Review Manual states that the accepted common name of each active ingredient must be listed on the product label, followed by the chemical name. For this reason, the following revision to the product label must be made;
- Under the "Ingredient Statement" change "Zinc, 2-pyridinethiol-1-oxide" to read "Zinc pyrithione (Zinc, 2-pyridinethiol-1-oxide).
- c. Under the "**STORAGE AND DISPOSAL**" section on page 2, delete the following language: "Do not reuse empty container".
- d. Under the "**STORAGE AND DISPOSAL**" section on page 2, change "tightly closes" to read "tightly closed".
- e. Under the "**CONTAINER DISPOSAL**" section on page 2, delete the following language: "Clean container promptly after emptying". In its place, insert the following: "Triple rinse (or equivalent)".
- f. Under the "**CONTAINER DISPOSAL**" section on page 2, delete the following language: "Before discarding, securely wrap container in several layers of newspapers and discard in trash" Since this product is not packaged in a pressurized container, nor is it a household product, this statement can be omitted.
- g. On page 3, under the **DIRECTIONS FOR USE** section, insert what specific "material preservative products" this registration is intended for in final end-use product formulations. This current reference is too vague.

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)

ZINC PYRION® POWDER MP

Manufacturing Use Product For Formulating Material Preservatives

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 11 2008

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

Active Ingredient:
Zinc, 2-pyridinethiol-1-oxide 95.0%
Inert Ingredients: 5.0%
Total: 100.0%

KEEP OUT OF REACH OF CHILDREN

43813-47

DANGER

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: 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. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN Probable mucosal damage may contraindicate the use of gastric lavage.	

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EPA Reg. No.: 43813- EPA Est. No.:

Manufactured for: JANSSEN PHARMACEUTICA
1125 Trenton-Harbourton Road
Titusville, NJ 08560

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER

Corrosive. Causes irreversible eye damage. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Do not breathe spray mists. Users must wear protective eyewear (goggles, safety glasses, or face shield), long sleeved shirt and long pants, socks, chemical resistant gloves and chemical resistant footwear. Users must wear a fit tested, NIOSH approved full-face respirator equipped with a combination organic vapor/P-100 prefilter. When mixing and loading, or cleaning equipment, wear a chemical resistant apron. Wash thoroughly after handling with soap and water, and before eating, drinking or using tobacco, after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARD

This pesticide is toxic to fish. 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.

CHEMICAL HAZARDS

Do not store or mix with strong oxidizing agents or strong (concentrated) acids. In case of contamination do not reseal container. If possible, isolate container in open or well-ventilated area. Fumes caused by contamination may be hazardous.

STORAGE AND DISPOSAL

Do not freeze. Store above 50 degrees F. Keep container tightly ^{closed} ~~(closes)~~ when not in use. Do not store with strong oxidizing agents.

Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticides, 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. ~~Do not reuse empty containers.~~

CONTAINER DISPOSAL

Non-refillable container. Do not reuse or refill this container. ~~Clean container promptly after emptying.~~ 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. ~~Before discarding, securely wrap container in several layers of newspaper and discard in a sanitary landfill.~~

ACCEPTED
with COMMENTS
in EPA Letter Dated

JUN 11 2008

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

43813-47

DIRECTIONS FOR USE

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

Use only for the formulation of material preservative products.

statement is too vague, be more specific

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

NOTICE OF WARRANTY

Janssen Pharmaceutica 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 Pharmaceutica. To the extent permitted by law, Janssen Pharmaceutica 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 Pharmaceutica 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
PMP ver. 01/08

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amended, for the pesticide,
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