

43813-48

8/6/2008

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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: 43813-48

Date of Issuance: AUG 6 2008

Term of Issuance: Conditional

Name of Pesticide Product: Zinc PYRION 40% Aqueous Solution Industrial Fungicide & Bactericide

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. 43813-48".

Signature of Approving Official: Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date: AUG 6 2008

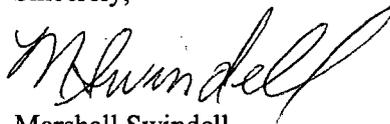
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- b. In the label, all references to "bacteria" or "bacterial" needs to be reflect what specific organism you intend to treat (i.e., stain causing bacteria, odor causing bacteria, etc...). The current language for bacteria (as it is expressed in your label) is broad and the user of this product could misconstrue that it is intended for treatment of organisms your registration is not licensed to treat.
- c. Under the "**CONTAINER DISPOSAL**" section on page 2, delete the following language: "Clean container promptly after emptying" and "Triple rinse container, then". In its place, insert the following: "Triple rinse (or equivalent)" promptly after emptying. This language is required per Pesticide Registration (PR) Notice 2007-4 "*Labeling Revisions Required by the Final Rule -Pesticide Management and Disposal; Standards for Pesticide Containers and Containment*".
- d. Under the "**CONTAINER DISPOSAL**" section on page 2, add the following language:
 - Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ 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 froth 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."
- e. In the label, all references to "algae and fungi" needs to be reflect what specific organism you intend to treat. The current language (as it is expressed in your label) is broad and the user of this product could misconstrue that it is intended for treatment of organisms your registration is not licensed to treat.

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)

SODIUM PYRION® 40% AQUEOUS SOLUTION INDUSTRIAL FUNGICIDE & BACTERICIDE

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

KEEP OUT OF REACH OF CHILDREN

WARNING

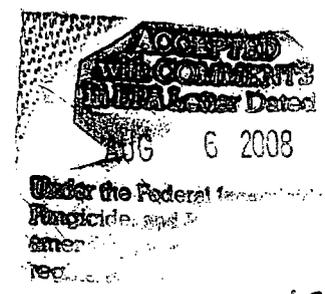
FIRST AID	
If in eyes	-Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. -Call a poison control center or doctor for treatment advice.
If swallowed	-Call a poison control center or doctor immediately 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 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	
Convulsions, if persistent, may be controlled by careful intravenous use of short-acting barbiturates. Probable mucosal damage may contraindicate the use of gastric lavage.	

Net Wt:

EPA Reg. No.: 43813-

EPA Est. No.:

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



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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.

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.

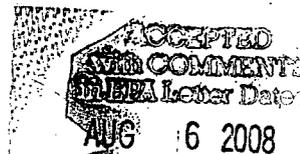
CHEMICAL HAZARDS

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 & DISPOSAL: 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. Clean container promptly after emptying. Triple rinse container, then 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.



Under the Federal Insecticide, and Rodenticide, and Fungicide Act, this pesticide is registered with:

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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 apply this product in a way that will contact workers or other persons. Do not use for applications involving direct or indirect food/drinking water contact.

IN AQUEOUS BASED FLUIDS SUCH AS METAL WORKING, CUTTING, COOLING AND LUBRICATING FLUIDS

To inhibit bacterial and fungal growth add an initial dose of up to 1250 ppm of this product (1.25 lbs. of this product to 1,000 lbs. of solution) to the solution by pouring from container and subsequent maintenance doses of up to 1250 ppm (1.25 lbs. of this product per 1,000 lbs. of solution) every 7-10 days or as needed. This product can be used at fluid to water ratios of 1:10 to 1:100. This product can be used at fluid to water ratios of 1:10 to 1:100. This product may be added to the fluid at the time it is prepared (diluted) or to the reservoir (sump) containing the fluid after it is put into use. If it is added to the reservoir, the fluid should be circulated after addition to ensure mixing. Contaminated fluid systems should be cleaned prior to the initial addition of this product. Drain the system, clean with cleaner designed for this purpose; rinse with water and refill with fresh fluid containing this product (up to 1250 ppm). Frequent checks (at least once a week) of the bacterial and fungal population in the system should be made using standard microbiological plate count procedures or any of the commercial "dip-stick" type devices. When the bacterial count reaches 10^7 and/or the fungal count reaches 10^3 organisms per ml, add additional product according to the above directions. If this does not reduce the bacterial and/or fungal count below the above value in 12-24 hrs., the fluid should be discarded and replaced after cleaning the system. Add this product to the fresh fluid according to the above directions. When adding fresh, diluted fluid to compensate for drag out or other losses, add this product to make-up fluid according to the above directions.

TO INHIBIT THE GROWTH OF BACTERIA AND FUNGI IN METALWORKING, CUTTING, COOLING AND LUBRICATING FLUID CONCENTRATES

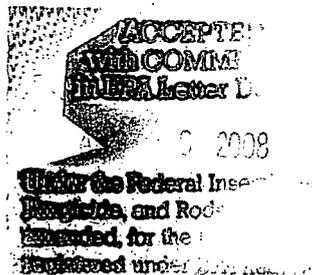
Add an amount that will give up to a 1250 ppm solution. The amount required in the concentrate will depend on the end use dilution. For example: If the desired level of this product is 1250 ppm and the end use dilution of the fluid is 5%, then a 2.5% concentration of this product is required in the concentrate ($1250 \text{ ppm} / 0.05 = 25,000 \text{ ppm}$ or 2.5%).

FOR THE IN-CAN PRESERVATION OF LATEX EMULSIONS USED IN ADHESIVES, CAULKS, PATCHING COMPOUNDS, SEALANTS, PASTES AND GROUTS

To inhibit bacterial growth in latex emulsions for a period of up to 1 year, a dosage of up to 1000 ppm of this product (1 lb. of this product per 1,000 lbs. of emulsion) is recommended. Product may be added at any time during the formulation procedure by pouring from the container.

IN AQUEOUS SYNTHETIC FIBER LUBRICANTS (SPIN FINISHES)

To inhibit the growth of bacteria and the formation of bacterial slime in synthetic fiber lubricants (spin finishes) for periods of 2-4 weeks during use, add 1250 ppm (1.25 lbs. per 1,000 lbs. of lubricant) of this product to the diluted lubricant. This product may be used in lubricant solutions containing 5-10% lubricant concentrate (water to lubricant ratios of 20-1 to 10-1). This product should be added by pouring from the container to the diluted lubricant in the dilution tank.



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IN AQUEOUS BASED INKS

To inhibit the growth of bacteria and fungi in inks such as aqueous based inks, printing solutions, pigment slurries or press cake, add up to 1250 ppm of this product. While the inks are in use, a concentration of 0.125% w/w of this product is necessary. The amount of this product to be added at the time of manufacture of the ink to obtain the above concentrations, at the time of use, will vary with the shelf-life of the ink. The table below shows the relationship.

Shelf-Life Ink (months)	% Sodium PYRION 40%
36	1.25
24	0.65
18	0.475
12	0.3125
8	0.25

To inhibit the growth of bacteria in neutral or slightly acidic aqueous based jet-printer inks for periods of up to 4 weeks while the inks are in use, add 0.75% w/w of this product to the ink at the time of manufacture. To avoid decomposition of this product during shelf-life of the ink, airtight packaging must be used. In all cases, this product may be added to the ink at any point in the manufacturing process by pouring from the container.

FOR THE DRY FILM PRESERVATION OF NATURAL AND SYNTHETIC ADHESIVES, LATEXES, URETHANE FOAMS, CAULKS, PATCHING COMPOUNDS, SEALANTS, ARCHITECTURAL PAINTS, INDUSTRIAL PAINTS AND COATINGS (Including wood coatings), PASTES AND GROUTS Addition of up to 5000 ppm (5 lbs. of this product per 1000 lbs. of formulation) of the active ingredient can inhibit microbial growth (bacteria and fungi) in the dry film of these products. This product can be added at any time during the formulation procedure. For example, sheet vinyl adhesives used in the installation of vinyl flooring can be preserved by the addition of 2100 ppm of this product (2.1 lbs. per 1000 lbs. of adhesive).

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.**

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PMP 01/08

ACCEPTED
 with COMMENTS
 in EPA Letter Dated
 AUG 6 2008
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide
 registered under EPA Reg. No
 43813-48