

43813-45

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:

43813-45

Date of

Issuance:

JUN 11 2008

Term of Issuance:

Conditional

Name of Pesticide Product:

Zinc PYRION Powder
Industrial
Microbiostat

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. 43813-45".

Signature of Approving Official:

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

Date:

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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. On page 3, in the "**For the Dry Film Preservation or Residential Paints against Fungus or Algae**" section, add what type of bacteria you intend to treat. In the text below the section, you have listed it as a treatment for "bacterial growth".
- d. 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).
- e. Under the "**PESTICIDE DISPOSAL**" section on page 2, delete the following language: "Do not reuse empty container".
- f. 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)".
- g. 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.
- h. In the label, all references to "other fungi" needs to be reflect what specific organism you intend to treat. The current language for "other fungi" (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)

Enclosure: (Stamped Label)

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ZINC PYRION® POWDER INDUSTRIAL MICROBIOSTAT

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

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.

KEEP OUT OF REACH OF CHILDREN

DANGER

43813-45

| 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 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 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 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. |
| <p>HOT LINE NUMBER:</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>NOTE TO PHYSICIAN</p> <p>Probable mucosal damage may contraindicate the use of gastric lavage.</p> | |

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.

DANGER

Corrosive. Causes irreversible eye damage. May be fatal if swallowed and absorbed through skin or inhaled. Do not get in eyes, on skin, or on clothing. Do not breathe dust. 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 and wash contaminated clothing and wash clothing before reuse.

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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

Handling conditions may form dust clouds which are susceptible to ignition by electrical (static) discharge. Ground container and personnel before transferring material. 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

PESTICIDE STORAGE: Do not store above 100°F. Keep container tightly closed when not in use. Do not store with strong oxidizing agents or strong (concentrated) acids.

PESTICIDE DISPOSAL: 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 burn 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 recycling, thoroughly wrap container in several layers of newspapers and discard in trash.~~

OK
anyway 's OK
(if burned, stay out of smoke)

DIRECTIONS FOR USE

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

A minimum cost effective use level recommendation can only be established through testing of a specific formulation intended for use in a specific application. Formulations differ in their composition and as a result, of their susceptibility to microbial attack. Conditions of use and the performance expectations differ from product to product. A warranted high performance preserved product, for example, that is under consideration for use in severe tropical environments, is likely to need a high dose of biocide. Testing at biocide use levels would be recommended at 3000, 4000 and 5000 ppm. As the product adds cost to the formulation and as performance requirements need to be met, laboratory and field tests are conducted to establish the antimicrobial performance of this product. An unwarranted preserved product that is not intended for use in severe environments would likely need a lower dose. Again, a recommendation would be made for testing at lower concentrations based on formulation, performance and cost considerations. We recommend that users contact Janssen Pharmaceutica for formulation assistance.

DRY FILM PRESERVATION: THIS PRODUCT PROTECTS THE APPLIED DRY FILM ITSELF AND DOES NOT PROTECT THE UNDERLYING SURFACE FROM ATTACK BY ALGAE OR BACTERIA.

For the Dry Film Preservation of Flooring Adhesives, Caulks, Sealants, Grouts and Patching Compounds:

Flooring Adhesives: For fungal control add 750 ppm of this product and for bacterial control add 2400 ppm. (Add 0.75 lbs. of this product to 1000 lbs. of adhesive to control fungus and add 2.4 lbs. per 1000 lbs. of adhesive to control ~~bacteria~~.)

Caulks/Sealants: For fungal control add 2083 ppm of this product and for ~~bacterial~~ control add 5000 ppm of this product. (Add 2.083 lbs. of this product per 1000 lbs. of caulk/sealant to control fungus, add 5.0 lbs. of this product to control ~~bacteria~~.)

Grouts/Patching Compounds: For fungal control add 1000 ppm of this product and for ~~bacterial~~ control add 4000 ppm of this product. (Add 1 lb. of this product to 1000 lbs. of grouts/patching compounds to control fungus and 4 lbs. of this product to control bacteria.)

For the Dry Film Preservation of Architectural and Industrial Non-Marine Paints and Coatings: Addition of up to 5000 ppm of this product can inhibit the growth of algae, bacterial slime, mildew, and ~~other fungi~~. It can be added at any time during the formulation procedure. For example, the dry film of a house paint having a density of 10 lbs. per gallon can be protected against the growth of algae, bacterial slime, mildew and ~~other fungi~~ by the addition of 5000 ppm of this product. (Add 5 lbs. of this product to 100 gallons of wet paint.)

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be included

For the Dry Film Preservation of Residential Paints Against Fungus or Algae:

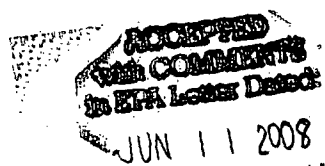
Use a minimum of 2500 ppm of this product. For maximum protection against the growth of fungus or algae, use 5000 ppm of this product. For control of ~~microbial~~ growth on the dry paint film surface, use 2500 ppm of this product. (Add a minimum of 2.5 lbs. of this product to 100 gallons of wet paint, with a density of 10 lbs. per gallon, to control fungus or algae. Add a maximum of 5.0 lbs. of this product to 100 gallons.)

For the Dry Film Preservation of Joint Compounds, Glazing Compounds and Wood Fillers: Addition of up to 5000 ppm (5.0 lbs. of this product per 1000 lbs. of formulation) of this product will 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 the Control of Mildew and ~~Bacteria~~ in Styrene Butadiene Rubber and Thermoplastic Resins Used in the Manufacture of the Following Products: Carpet Fibers; Carpet Backings; Rubber or Rubber Backed Bath Mats; Foam Underlay for Carpets; Synthetic, Non-Leather Materials; Foam Stuffing for Cushions and Mattresses; Wire and Cable Insulation; Vinyl, Linoleum and Synthetic Floor Coverings; Wall Coverings; Plastic Furniture; Athletic Flooring and Mats; Mattress Liners; Covers or Ticking; Molding; Mats; Gaskets; Weather Stripping; Coated Fabrics for Furniture Cushions, Boat Covers, Tents; Tarpaulins; Awnings; Non-Surgical Rubber Gloves; Garbage Bags, Refuse Containers; Bathtub Appliqués; Garden Hose; Non-Potable Water Pipe; Ductwork, air filters, air filtration components and air filtration media for industrial, hospital, residential, and commercial heating and cooling; conveyor belts; Shower Curtains; Sponge or Fiber Mops; Household Use Sponges; Toilet Brush Receptacles, Toothbrush Receptacles (Non Bristle Contact); Non-Medical Scrub Brushes; Sink Mats and Drain Boards; Storage Containers; Soap Dish Holders; Towel Bars and Components of Footwear.

Addition of up to 4000 ppm (4 lbs./1000 lbs. of formulation) of this product can inhibit the growth of mildew & ~~fungi~~ in styrene butadiene rubber & thermoplastic resins such as vinyl chloride-vinyl acetate copolymers, polyurethanes, polyamides, polyolefins, polystyrene, polyesters and acrylonitrile copolymers. It can be added at a time during the formulation procedure that will insure uniform distribution throughout the polymer system. Add by pouring or by use of metering equipment. For example, to inhibit mildew growth in polyurethane footwear components, add 2000 ppm (2 lbs./1000 lbs. of formulation) of this product to the polyurethane formulation.

For the In Can Preservation of Latex Emulsions, Clay, Mineral, Pigment and Guar Gum Slurries Used in the Manufacture of Adhesives, Caulks, Patching Compounds, Sealants and Grouts: A dosage of up to 5000 ppm is recommended to control ~~microbial~~ and fungi. This dosage is equivalent to 5 lbs. of this product per 1000 lbs. of slurry. It may be added at any time during the formulation procedure.



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

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To Inhibit the Growth of ~~Bacteria~~ and Fungi in Dry Wall and Gypsum, Pearlite, Plaster-Like, Mineral Based, or Cellulose Derived Building Materials Used in the Manufacture of Ceilings, Ceiling Tile, Walls and Partitions: Addition of up to 4000 ppm of this product (4 lbs. of product per 1000 lbs. of the formulation, i.e. wet slurry) will inhibit the growth of ~~bacteria~~ and fungi. It can be added at any time during the formulation procedure. Alternatively the product may be added to latex or other types of coating systems routinely applied to the surfaces of walls, ceiling tiles, partitions, etc. at the same dosage as above.

To Inhibit ~~Bacterial~~ and Fungal Growth on Laundered Fabrics: Fabrics to be treated include nylon, polypropylene, polyethylene, polyesters, cellulose and blends of these polymers. At a sour density of 8.3 pounds per gallon, add 3-9 ounces of this product per 1000 lbs. dry weight of fabric to reach a use level of 19-56 ppm. Apply to the sour operation and run for a minimum of five minutes. Product is to be used in industrial applications. Product is not intended for use in residential, commercial or institutional settings.

INDIRECT FOOD CONTACT USES:

To Control Growth of ~~Bacteria~~ and Fungi in Adhesives Used For Food Packaging: For food packaging adhesives, at use temperatures up to 120°F, and subject to Good Manufacturing Practices, including the conditions specified in 21 CFR 175.105 (a) and (b), add a dosage of 750 ppm to a maximum of 1000 ppm of this product (0.75 to 1.0 lb. of this product per 1000 lbs. of food packaging adhesive) at a point where thorough mixing will take place.

To Control the Growth of ~~Bacteria~~ Fungi on Food Contact Surfaces Made from Polymers: Do not incorporate this product into any food contact polymer unless the subject food contact polymer is approved and listed in 21 CFR, Parts 174 through 186 (inclusive), or in the United States Food and Drug Administration's "Food Contact Substance Notification System". Restricted to use applications at or below room temperature. Any incorporation of this product into any food contact substance (including but not limited to non-polymer substances) other than an approved and listed food contact polymer is prohibited. For incorporation into articles made from, or coated with FDA approved polymers. Applications include food processing equipment, conveyor belts, utensils, and storage containers. Add 750 ppm to a maximum of 1000 ppm of product (0.75 to 1.0 lbs. of this product per 1000 lbs. of polymer) at a point where thorough mixing will take place.

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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ADD COMMENTS
EPA Letter Dated

PMP ver. 01/08

JUN 11 2008

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

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